
**United States Court of Appeals
For the Federal Circuit**

ARTHROCARE CORPORATION,

*Plaintiff/Counterclaim Defendant-
Appellee,*

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

*Defendant/Counterclaimant-
Appellant.*

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE IN 01-CV-504,
CHIEF JUDGE SUE L. ROBINSON

NON-CONFIDENTIAL JOINT APPENDIX

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CONFIDENTIAL MATERIAL OMITTED FROM
THE NON-CONFIDENTIAL JOINT APPENDIX

The material omitted from the Non-Confidential Joint Appendix relates to confidential agreements executed by ArthroCare Corporation, documents filed under seal with the district court, and Smith & Nephew, Inc.'s counterclaim, the dissemination of which the district court has restricted.



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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

**DEFENDANT SMITH & NEPHEW'S RENEWAL OF MOTION FOR
JUDGMENT AS A MATTER OF LAW PURSUANT TO FED. R. CIV. P. 50(b)**

Defendant Smith & Nephew, Inc. ("Smith & Nephew") renews its motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 59(b). In support of this motion, Smith & Nephew has filed a memorandum and a declaration simultaneously herewith.

Dated: June 30, 2003

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

[PROPOSED] ORDER

The Court having considered Smith & Nephew's Rule 50(b) Motion for Judgment as a Matter of Law, and good cause having been shown therefore,

IT IS HEREBY ORDERED this _____ day of _____, 2003 that:
Smith & Nephew's Motion is GRANTED.

UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of June, 2003, a true and correct copy of the Defendant Smith & Nephew's Renewal Of Motion For Judgment As A Matter Of Law Pursuant To Fed. R. Civ. P. 50(b) was caused to be served on the attorneys of record at the following addresses as indicated:

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION
FOR JUDGMENT AS A MATTER OF LAW

Dated: June 30, 2003

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I. NATURE AND STAGE OF THE PROCEEDINGS

For the Nature and Stage of the Proceedings, please see Smith & Nephew's Opening Brief in Support of Its Motion for a New Trial, filed concurrently.

II. SUMMARY OF THE ARGUMENT

ArthroCare failed to introduce evidence to show that Smith & Nephew itself directly infringes, contributes to the infringement by others, or actively induces infringement by others of any of the claims in suit. Since ArthroCare bears the burden of proving each of these allegations, its failure to carry these burdens requires judgment as a matter of law (JMOL) for Smith & Nephew on the following issues:

- (1) Neither Smith & Nephew's accused probes nor the use of these probes infringe the patents-in-suit under the doctrine of equivalents.
- (2) Smith & Nephew does not directly infringe the method claims of the '592 and '882 Patents.
- (3) Smith & Nephew's accused probes do not infringe the claims of the '536 patent because ArthroCare failed to prove these probes include all of the elements required by the '536 patent within an "electrosurgical system" as required by the claims.
- (4) Smith & Nephew's accused probes do not infringe the claims of the '592 patent because ArthroCare failed to prove that the accused probes satisfy the requirement that "the return electrode is not in contact with the body structure" or the requirement of "spacing a return electrode away from the body structure". Similarly, Smith & Nephew's accused probes do not infringe claim 47 of the '536 patent because ArthroCare failed to prove the return electrodes on the probes are "sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue".
- (5) Smith & Nephew's accused probes do not infringe the claims of the '882 patent because ArthroCare failed to prove that the accused probes have "an electrode terminal," "a return electrode," "an active electrode," and "an electrically conducting terminal," all of which are required because the Certificate of Correction is not valid.

(6) Non-suction models of Smith & Nephew's Saphyre products do not infringe claim 54 of the '882 patent because they do not "evacuat[e] fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal".

(7) Smith & Nephew is not liable for contributing to the infringement of any claim of the patents-in-suit.

(8) Smith & Nephew is not liable for inducement of infringement of any claim of the patents-in-suit.

Moreover, no reasonable jury could find that Smith & Nephew did not prove—with clear and convincing evidence—that each of the asserted claims is invalid as anticipated and/or non-enabled. Entry of JMOL is therefore appropriate. Specifically:

(9) ArthroCare presented no expert testimony or any other evidence to rebut Smith & Nephew's evidence that six prior art references anticipate the asserted claims. Nor did ArthroCare dispute the prior art status of any of Smith & Nephew's invalidating art.

(10) Rather than present an answering case on validity, ArthroCare's counsel relied exclusively on an incomplete and cursory cross-examination of Smith & Nephew's expert, Dr. Taylor. Because this cross-examination fell far short of establishing any basis on which a reasonable jury could have found for ArthroCare on validity, Smith & Nephew is entitled to judgment as a matter of law. ArthroCare merely threw up a smoke screen of alleged "concessions by Dr. Taylor," and succeeded in confusing the jury. This confusion is highlighted best by the Pao '499 patent, which Smith & Nephew showed anticipated claims 46 and 56 of the '536 patent. ArthroCare's cross-examination on this point was limited to an element present only in claim 47, against which Pao *was not even asserted*. Nonetheless, the jury—apparently confused by ArthroCare's misleading cross-examination and argument—found Pao did not anticipate claims 46 and 56.

(11) Likewise, ArthroCare presented no evidence to rebut Smith & Nephew's clear and convincing evidence that the '882 patent is invalid for lack of enablement. ArthroCare

asserts that the '882 patent discloses a new phenomenon of physics called "coblation" (as assert it ArthroCare must, because otherwise the '882 patent merely describes well-known electrosurgical techniques from the prior art). But despite saying that this "coblation" phenomenon is highly dependent on very exact parameters, the specification does not describe those parameters with specificity. Thus, to the extent that the '882 is not invalid as being anticipated by the prior art, it is invalid for lack of enablement.¹

III. CONCISE STATEMENT OF FACTS

The facts related to each of the grounds upon which Smith & Nephew moves for judgment as a matter of law are addressed in each of the corresponding sections of the argument.

IV. ARGUMENT

A. Applicable Legal Standards

Entry of judgment as a matter of law (JMOL) is appropriate where "the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998). The question is not whether there is "literally no evidence" supporting the non-moving party, *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 345, 350-51 (D. Del. 2000), but whether the evidence *reasonably* supports the jury's verdict. *Gomez v. Alleghany Health Servs. Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995).

District courts grant JMOL if, upon the record before the jury, reasonable jurors could not have reached that verdict. Fed. R. Civ. P. 50; *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984). In deciding whether to grant JMOL on any issue after a jury has returned a verdict, the court determines whether substantial evidence exists in the record to support the jury's verdict when the correct legal standard is applied. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975 (Fed.

¹ In addition to the specific grounds of JMOL discussed in detail herein, Smith & Nephew also renews and reserves all of its arguments with respect to claim construction as set forth in its claim

Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Substantial evidence is the quantum of evidence that reasonable jurors would accept as adequate to support the finding under review. *Perkin-Elmer*, 732 F.3d at 893.

JMOL should be granted if "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a); see *Northview Motors, Inc. v. Chrysler Motors Corp.*, 227 F.3d 78, 88 (3rd Cir. 2000). In a patent infringement action, "JMOL of non-infringement is properly granted if no reasonable jury could have concluded that a limitation recited in the properly construed claims is found in the accused device, either literally or under the doctrine of equivalents." *Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc.*, 248 F.3d 1303, 1309 (Fed. Cir. 2001).

To overcome a motion for JMOL, the non-moving party must point to "substantial evidence" to support a finding in its favor. See *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1329 (Fed. Cir. 1991). Merely "offhand and conclusory statements" are not sufficient to overcome the motion. *Id.* at 1327.

The patent owner bears the burden of proving infringement (by a preponderance of the evidence) that the accused device, or use of that device, has all the limitations of the asserted claims. *Novartis Corp. v. Ben Venue Labs., Inc.* 271 F.3d 1043, 1046 (Fed. Cir. 2001).

B. Smith & Nephew's Accused Probes And The Use Of These Probes Do Not Infringe The Patents In Suit Under The Doctrine Of Equivalents

ArthroCare introduced *no* evidence of infringement under the doctrine of equivalents, and JMOL on this issue should be granted. ArthroCare attempted to introduce evidence regarding equivalent infringement for the first time during redirect examination of its expert Dr. Goldberg. The Court properly excluded this belated "rebuttal" evidence. (D.I. 415 at 1144). In making the ruling, the Court stated that ArthroCare should have brought the matter up during direct examination and that, even if it had, the testimony would not have been permitted because the equivalence analysis in Dr. Goldberg's report was insufficient. (*Id.*). Thus, judgment as a

construction brief (D.I. 246 and 282), to the extent that the Court adopted a different claim construction from that set forth by Smith & Nephew.

matter of law that Smith & Nephew does not infringe any claim of any patent-in-suit under the doctrine of equivalents should be granted.

C. Smith & Nephew Does Not Directly Infringe The Method Claims Of The '592 And '882 Patents

ArthroCare failed to provide *any* evidence that Smith & Nephew itself uses or has used the Saphyre, ElectroBlade, or Control RF probes in surgery as required by the claims of the '592 and '882 method patents. "A method claim is directly infringed *only by one practicing* the patented method." *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) (emphasis added). ArthroCare has offered no evidence from which a reasonable jury could conclude that Smith & Nephew uses its Saphyre, ElectroBlade, or Control RF probes to perform each step of the methods covered by ArthroCare's claims. Indeed, the only evidence at trial was that Smith & Nephew does not use the accused probes. (See, e.g., D.I. 414 at 961). Thus, the Court should enter judgment as a matter of law that Smith & Nephew does not directly infringe any claim of the '882 or '592 patent.

D. The '536 Patent

1. JMOL Of Non-Infringement Of The Claims Of The '536 Patent Is Appropriate Because ArthroCare Failed To Prove That These Probes Are Used As Part Of The "Electrosurgical System"

Claim 45 of the '536 patent, and the claims that depend from it (asserted claims 46, 47, and 56) claim an electrosurgical system, which includes its own fluid supply. Specifically, the '536 patent is directed to an electrosurgical system that can be used in open surgery -- e.g., surgery in a dry environment -- because "[e]lectrically conductive liquid, such as isotonic saline, is directed through a fluid path past a return electrode and to the target site to generate a current flow path." (JTX-1, col. 3, lines 26-30). As described in the Summary of the Invention:²

The above described method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, laparoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode.

² The Summary of the Invention is an optional part of the patent application. "Such summary should, when set forth, be comensurate with the invention as claimed..." 37 C.F.R. §1.73.

(*Id.* at col. 3, lines 37-41). This is distinct from arthroscopic surgery, in which the joint is filled with saline (which is a biocompatible fluid) in order to move the soft tissue out of the way of the surgeon and wash out debris that is produced during the operation. Such a supply of saline in arthroscopic surgery is completely separate from any electrosurgical instrument, and the saline is typically supplied by either an IV bag or a separate system such as the Intellijer.

The Court construed the term "system" in claim 45 of the '536 patent to mean "an assemblage or combination of things or parts forming a unitary whole." (D.I. 354). The claims require that the system include several elements, including "an electrically conducting fluid supply for directing fluid to the target site, "which thus must all be part of the "unitary whole." However, ArthroCare's expert ignored the Court's construction and the requirement that an electrically conducting fluid supply for directing fluid to the target site be part of the claimed system -- i.e., as part of the "unitary whole"—such that the system could be used in open surgery.

Dr. Goldberg testified:

Q. Now, is the Saphyre bipolar ablation probe used as part of an electrosurgical system?

A. Yes, sir, it is.

Q. Now, is the electrically conductive fluid supply physically connected to this probe that we've been looking at?

A. Not this probe, sir.

Q. So how is it then that this probe is part of a system that includes electrically conductive fluid?

A. Again, *my understanding of a system* is that things don't have to be physically in contact. Another example that just came to mind is when we have a wireless computer system or an audio system, the mouse doesn't have to be connected by a wire to the computer to be part of the same system. They're all functioning to put in the data or to listen to the stereo. *So it doesn't have to be part of, physically connected.* The electrical fluid in the joint will get there. The surgeon has to fill the entire joint to distend it and the fluid will get there. It's all part of the system, sir.

(D.I. 411 at 398-399) (emphasis added).

In his testimony, Dr. Goldberg clearly failed to apply the Court's construction of the term "system." He never described how the Saphyre and a separate fluid supply form an "assemblage or combination of things or parts forming a unitary whole." Instead, he actually disavowed and disagreed with the Court's claim construction, and said that "it doesn't have to be part of, physically connected." (*Id.*). Since he did not agree with the Court's claim construction, he obviously did not provide any evidence that was in accordance with the Court's claim construction. Instead, all he said was that "the fluid will get there." (*Id.*). But he didn't say how.³

These omissions became even more apparent during Dr. Goldberg's testimony regarding the individual claim elements. For each of the accused products, Dr. Goldberg testified that the product comprises the first two elements of the system required by claim 45. However, Dr. Goldberg's analysis ignored the third element of the system, the electrically conducting fluid supply. For the Saphyre, Dr. Goldberg testified:

And there is electrically conducting fluid supplied because this is arthroscopy and there is electrically conductive fluid delivered by the surgeon and the people in the operating room to the joint.

(D.I. 411 at 447). This testimony is very misleading because Dr. Goldberg, and ArthroCare continually focused on arthroscopic surgery. But the claims are not so limited. In fact, if one were to use the Saphyre in, for example, an oral surgery such as described in the Summary of the Invention of the '536 patent⁴ the device would not work because the Saphyre does not have a fluid supply as part of its system. Dr. Goldberg actually recognized this in his experimentation with the Saphyre product (*Id.* at 416):

Q. You mentioned that you also tested the Saphyre when the return electrode was in air and the active electrode was in saline; is that right?

A. Yes, sir.

Q. Can you describe for the jury what happened when you used the Saphyre probe in that mode?

³ Likewise, for the Control RF and ElectroBlade products, Dr. Goldberg failed to provide any evidence that the products are a "system" as required by Claim 45.

A. It didn't work. Thus, any testimony that the Saphyre probe includes the fluid supply simply because it is designed for arthroscopic surgery is misleading and incorrect.

For the Control RF, Dr. Goldberg did not even mention a fluid supply and simply said

(*Id.* at 448):

There is electrically conductive fluid, as well as a current flow path when the generator is on.

Similarly, for the ElectroBlade, instead of describing a fluid supply (Tr. at 449):

Up the shaft is a return electrode. It's connected to the generator and it's in electrically conductive fluid and there is a current flow path through the electrically conductive fluid at the time the generator was activated.

While the Smith & Nephew probes are used in the presence of saline or other electrically conducting fluids, that fluid is not supplied to the target site by the probes. (D.I. 415 at 976 and 1013). Fluid, typically from an IV bag, is instead introduced by a separate and distinct piece of medical equipment such as the cannula that is also used for the videoarthroscope. (D.I. 414 at 815-16; D.I. 268, Ex. 43). That separate piece of equipment is not part of the "electrosurgical system." The Smith & Nephew probes and fluid supply are not part of the same assemblage or combination of things or parts forming a "unitary whole."⁵

Moreover, ArthroCare introduced no evidence that the alleged system included a fluid supply "for directing fluid to the target site." Instead, the testimony was uncontroverted that the purpose of the fluid supply used with the Smith & Nephew probes was instead to flood the inside of the joint in order to move soft tissue back and also to wash out debris. (D.I. 414 at 780-81 and 790)

⁵With respect to ArthroCare's attempt to argue that the separate Smith & Nephew Intellijet fluid supply system was part of an "electrosurgical system," that evidence was limited to the "System Configuration" contained in the ElectroBlade IFU. (D.I. 411 at 497; PX 189). However, Karen Drucker testified that this System Configuration is for compliance with European regulations. Thus, to the extent this evidence is taken to support the inference that the ElectroBlade and the Intellijet, used in this configuration, are an "electrosurgical system," it is only evidence for their use in Europe. Moreover, Ms. Drucker explained that IFU showed that the Intellijet system was not completely separate from the ElectroBlade system. (D.I. 415 at 1018).

Since the probes each lack the fluid supply element as part of the electrosurgical system as required by the claims, they cannot directly infringe these claims.⁶ See *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1358-59 (Fed. Cir. 2000); *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991) ("To establish infringement, every limitation set forth in a patent claim must be found in an accused product or process exactly or by substantial equivalent."). Because ArthroCare failed to present evidence by which a reasonable jury could find that any of the accused products satisfies the "system" requirement of claim 45 that is incorporated into asserted claims 46, 47, and 56, JMOL of non-infringement of these claims is proper.

E. The '592 Patent

- 1. Smith & Nephew's Accused Probes Do Not Infringe The Claims Of The '592 Patent Because ArthroCare Has Failed To Prove That The Accused Probes Satisfy The Requirement That "The Return Electrode Is Not In Contact With The Body Structure" Or The Requirement Of "Spacing A Return Electrode Away From The Body Structure"**

Claim 1 of the '592 patent requires "positioning a return electrode ... such that [it] is not in contact with the body structure" and claim 23 requires "spacing a return electrode away from the body structure." The Court construed these terms to mean that "the return electrode is not to contact the body structure *at all during the performance of the claimed method.*" (D.I. 353) (emphasis in original).⁷

ArthroCare's expert, Dr. Goldberg, again ignored the Court's claim construction when he rendered his opinion that the Smith & Nephew probes infringe:

Q. Now, does that portion of the claim as construed by the Court require that the Saphyre bipolar ablation probe return electrode never contact the tissue during the course of an entire arthroscopic procedure?

A. No, it doesn't. Mr. Bobrow, you raised a very important --

⁶And, as discussed above, ArthroCare has completely failed to provide any evidence that a separate fluid supply is in any way equivalent to a unitary whole.

⁷Claim 47 of the '536 patent includes a similar limitation which reads "the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue." Thus, Smith & Nephew submits that ArthroCare failed to prove infringement of that claim for the same reasons.

* * *

A. I was about to try to explain to the members – the ladies and gentlemen of the jury as to why this is a very important point. The claim is talking about a method for applying electrical energy, so the issue is whether or not a device infringes when the electrical energy is not — when it is being applied. There are a lot of parts to a surgery, including putting in the camera, taking out the camera, taking care of the patient that don't involved applying electrical energy. So the key is, is this method being infringed when it's fulfilling the claim which is when the energy is being applied? *So the only way not to infringe this claim with the device is to make sure that the return electrode —*

* * *

is always in contact when the energy is on. And as the videotape and Mr. Marsden suggested, very clearly there is occasional contact frequently, but often there isn't. The probe is designed to enable they're not being contact. If it's not in contact, it's being infringed.

(D.I. 411 at 421-22) (emphasis added).

Dr. Goldberg's testimony that the use of Smith & Nephew's products infringe the claims of the '592 patent is based on ArthroCare's previously-rejected interpretation of the claim term, rather than the Court's construction. Specifically, by stating that the "only way not to infringe this claim with the device is to make sure that the return electrode ... is *always* in contact when the energy is on," Dr. Goldberg is applying ArthroCare's temporal limitation that the Court specifically rejected. (D.I. 352, p. 6) ("Both parties have proposed a claim construction that improperly imports a time limitation into the claim. The claim limitation in dispute has no relation to the time required to perform the method.").

The following chart demonstrates how Dr. Goldberg has ignored the Court's construction and continued to apply ArthroCare's original and now rejected construction:

ArthroCare's Rejected Argument	Dr. Goldberg's Testimony
"Smith & Nephew's proposed experts have not offered any evidence or opinion that the return electrode of the Saphyre is <i>always contacting</i> patient tissue during use." (D.I. 252 at 12) (emphasis added).	"the only way not to infringe this claim with the device is to make sure that the return electrode ... is <i>always in contact</i> when the energy is on." (Tr. at 421-22) (emphasis added).

Further the Court's claim construction refers to the performance of *all three* steps of the method. Only one of those steps requires the application of RF energy. However, Dr. Goldberg and ArthroCare completely ignored the first step of the method — "positioning the electrode

terminal into at least close proximity with the target site." (JTX-3, claims 1 and 23). Both ArthroCare and Dr. Goldberg ignored return electrode contact with the tissue when the probe is being positioned before the RF energy is being applied. This misleading view is evident when Dr. Goldberg states "when we're talking about *activation of energy, which is what the claims are referring to, they're limiting it to two very small periods of time.*" (D.L. 415 at 1119) (emphasis added). But the Court's claim construction expressly rejected any time limit, and certainly is not limited to the time period of activation of energy. Thus, Dr. Goldberg's assertion of "what the claims are referring to" is simply incorrect.

In fact, ArthroCare introduced absolutely no evidence that the method of using the accused products met these limitations of the '592 patent under the Court's claim construction. Indeed, even all of its cross-examination of Smith & Nephew's witnesses was based upon the erroneous claim construction which ArthroCare had proposed, and which the Court had rejected. (See, e.g., D.L. 415 at 983 and 1035-36).

Instead, under the Court's claim construction, *all* of the evidence at trial showed that the return electrode frequently contacted tissue at various times when one or more of the three steps of the method was being practiced. As can be seen in the various sales-training videos (DTX 315, DTX 316, and DTX 897), the three steps of the method are continually being practiced -- if the power is not being applied, the active electrode is being positioned for the next time that the surgeon applies the power.⁸ Thus, Dr. Goldberg's and ArthroCare's evidence was not based on the Court's claim construction and cannot support a verdict of infringement.

The confusion regarding the time period in which one analyzes the use of the accused devices was further compounded in ArthroCare's closing argument, in which Mr. Bobrow misleadingly argued:

⁸ ArthroCare attempted to mislead the jury when it twicestopped the Saphyre video at an instant in the middle of the performance of the claimed method when the return was not contacting tissue (D.L. 415 at 985), and suggested this was proof of infringement. The Court's claim construction was clear: the return electrode is not to contact the body "at all" during performance of the method and the method is not complete until all three steps are performed.

There is no minimum time period. If energy is applied for three seconds and the return electrode is not in contact for those three seconds, and the active electrode is close to the tissue, and RF energy is applied and all the other language is met, this is satisfied. This is satisfied.

Now, *if in the fourth second, it hits the tissue, well, then it's not practicing the method.* But if in the fifth and sixth seconds, it's away from the tissue again, then it is. There is no time limitation.

I can perform this method for two seconds. I could perform it for two minutes. There is no time limitation.

(Tr. at 1580-81) (emphasis added). While this Court indeed held that there were no temporal limitations to the performance of the claimed method, it also held that that "the return electrode is not to contact the body *at all during the performance of the claimed method.*" (4/9/03 Memorandum Order at 2, D.I. 353) (emphasis in original). Thus, if the energy was still on when the return electrode "hits the tissue" in the fourth second of Mr. Bobrow's example, there would be no infringement no matter what happened over the first three seconds.

Finally, ArthroCare presented no direct evidence that doctors do not touch the return electrode to tissue during use of the accused products. In fact, ArthroCare presented no evidence that the doctors who used the devices actually used them to perform the method of the asserted claims. Dr. Goldberg's only opinion, and all that the evidence showed, was that "doctors have used the Saphyre after the [patents' issue] date in the United States." (Tr. at 462; *see also* Tr. 465-66 and 470). There is not one shred of evidence that the uses described by Dr. Goldberg were actually directly infringing the methods of the '592 patent.

Dr. Goldberg ignored the Court's claim construction and presented its infringement case based on ArthroCare's long rejected argument of what the claim means. ArthroCare thus failed to present any relevant evidence by which a reasonable jury could find that the use of any of the three accused products satisfies the return electrode "not in contact" requirement. JMOL of non-infringement is proper.

F. The '882 Patent

1. There Is No Infringement Of The '882 Patent Because The Certificate Of Correction Is Not Valid

The Certificate of Correction broadened the scope of claim 1 of the '882 patent by reducing the number of electrodes required by the claim. Prior to the Certificate of Correction, claim 1 of the '882 patent required four electrodes: an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal. (JTX-2 at col. 24 lines 8-12). After the Certificate of Correction, the claim required only two electrodes: an electrode terminal and a return electrode. (See Certificate of Correction attached to JTX-2).

It was undisputed at trial that if the Certificate of Correction had not been obtained—or was invalid—Smith & Nephew would not infringe the '882 patent, because the accused Control RF and Saphyre products have only two electrodes. (See testimony of ArthroCare's expert, Dr. Goldberg, (Tr. 1110) (D.I. 415)).⁹

As set forth in Smith & Nephew's brief in support of its motion for a new trial (filed concurrently), Smith & Nephew contends that the issue of validity of the Certificate of Correction should never have been submitted to the jury. However, since it was submitted to the jury, and there was no evidence supporting the jury's finding that the Certificate of Correction was valid, JMOL should be entered for Smith & Nephew on this issue.

The controlling case on the validity of the Certificate of Correction is *Superior Fireplace v. Majestic Products*, 270 F.3d 1358, 1368 (Fed. Cir. 2001). In that case, the Federal Circuit explained that corrections are permitted under 35 U.S.C. § 255 only in order to correct "a mistake of a clerical or typographical nature, or of minor character, which was not the fault" of the PTO. As explained in *Superior Fireplace*, a mistake "of a minor character" may not broaden the claim. 270 F.3d at 1376. Since the Court has already determined here that the Certificate of Correction broadened the claim (D.I. 417 at 1550-51), and ArthroCare's expert Dr. Goldberg admitted as

⁹ ArthroCare tried to create some confusion with the jury by having its expert, Dr. Goldberg, testify that the ElectroBlade product might be viewed as having more than two electrodes. (Tr. at 1111-13). However, this testimony was irrelevant and confusing, since the '882 patent had never

much (D.I. 415 at 1109-11), in order for the Certificate of Correction to be valid, the alleged "mistake" that was "corrected" must therefore qualify as one "of a clerical or typographical nature."

A Certificate of Correction can validly correct a clerical or typographical mistake only if a review of the file history reveals (1) there was indeed a "clerical or typographical mistake" and (2) it is both "manifest" that there is an error to be corrected and it is also "manifest" how to correct the error. 270 F.3d at 1370.

In Smith & Nephew's Opening Brief in Support of its Inequitable Conduct Case, Smith & Nephew showed how the Certificate of Correction at issue was actually obtained by ArthroCare's in-house attorney, John Raffle, in order to broaden the claim so that it could sue Ethicon — in other words, that there was no "mistake" involved at all. (D.I. 442 at 35). However, putting that issue aside, the prosecution history and the testimony from trial shows that no reasonable juror could have found that either the alleged mistake or the solution for correcting the alleged mistake was "manifest," for at least the following four reasons:

a. A Simultaneous Complementary Change to Claim 26 Shows That There Was No Manifest "Error" in Claim 1

Mr. Raffle filed the Request for Certificate of Correction on December 17, 1997. (DTX 306 at 234-35).¹⁰ In the Request for Certificate of Correction, Mr. Raffle represented that the alleged "errors" being corrected arose in connection with an amendment he filed during prosecution of the '882 patent application on March 25, 1997. (DTX 306 at 200-10). One of the alleged errors involved amending application claim 23 (which became patent claim 1) so that the claim required both an "active electrode" and an "electrode terminal." However, in that very same amendment, Mr. Raffle also amended application claim 52 (which became patent claim 26) so that it also required both an "active electrode" and an "electrode terminal." Thus, Mr. Raffle

even been asserted against the ElectroBlade product. (See, e.g., Tr. at 1214; see also D.I. 405 at 3).

¹⁰ Although the Request refers to claim "23," it is clear that this was a mistaken reference to the application claim number, and that the request sought to change claim 1. (DTX 306 at 239; D.I. 417 at 1510).

simultaneously amended the claims that would become claims 1 and 26 so that they both included an "active electrode," and an "electrode terminal," (as well as a "return electrode"). (See D.I. 417 at 1511-13):¹¹

Q. So just to review, in Claim 1, in the second — in the third line, you changed active electrode to electrode terminal; right?

A. Yes.

Q. And in the third line of Claim 26, you left active electrode all alone. You didn't change it; right?

A. That's correct.

Q. Okay. And then in the sixth line of Claim 1, you left active electrode again all alone, didn't change it; right?

A. Correct.

Q. And in the corresponding sixth line of Claim 26, you changed active electrode to electrode terminal; right?

A. Correct.

Thus, anyone reviewing the file history of the '882 patent would see that one instance of "active electrode" was changed to "electrode terminal" in both claims 1 and 26, whereas the other instance of "active electrode" in both claims 1 and 26 was left unchanged. Accordingly, no reasonable juror could find that it was "manifest" that the term "active electrode" was in error in claim 1, or that it was "manifest" that "active electrode" should be changed to "electrode terminal" in claim 1.

b. The Amendments To Claims 1 And 26 Created Inconsistent Antecedent Basis Problems — And There Was No Way Of Knowing Which Was Correct

ArthroCare has argued that an error in antecedent basis in claim 1 supports the notion that the so-called "mistake" was "manifest."

Generally, the first time an element is referred to in a claim, an indefinite article ("a" or "an") is used, whereas thereafter, a definite article ("the" or "said") is used to show that the same

¹¹ A side-by-side comparison of Mr. Raffle's amendments to application claims 23 and 52 (which became patent claims 1 and 26 respectively) was used to cross-examine Mr. Raffle at trial. (Exhibit A to accompanying Declaration of William J. Marsden, Jr.)

claim element is being described. To use a definite article for the first mention of a claim term is sometimes referred to as improper "antecedent basis."

In this case, as a result of the amendment Mr. Raffle made to claim 1, the term "active electrode" did not have a proper antecedent basis. (JTX-2, col. 24, lines 5-12). However, anyone reviewing the file history would see that there were other instances in the claims of the '882 patent in which there was an improper antecedent basis. For example, as a result of the amendment Mr. Raffle made to claim 26, at the very same time as his amendment to claim 1, the term "electrode terminal" also did not have a proper antecedent basis. (JTX-2, col. 25, lines 24-30). Thus, anyone reviewing the file history for the '882 patent would see that (a) Mr. Raffle amended claim 1 to include both an "active electrode" and an "electrode terminal," but did not provide proper antecedent basis for the "active electrode," and (b) at the very same time, he amended claim 26 to include both an "active electrode" and an "electrode terminal," but did not provide proper antecedent basis for the "electrode terminal."

Given this, it would not be possible for one reviewing the file history to determine (1) whether any error occurred at all, or if so (2) whether the error was in claim 1 or 26 or both, or (3) whether "electrode terminal" should be "active electrode" or "active electrode" should be "electrode terminal." Certainly, no reasonable juror could possibly find that any of this was "manifest." If anything, to the extent an antecedent basis error would be recognized at all, the most obvious way to correct the error would be to simply change "the" to "an" to correct the antecedent basis.

c. ArthroCare's Failure To Object To The Examiner's Statement Of Reasons For Allowance Shows That There Was No "Manifest Error" In Claim 1

Further, anyone reviewing the file history would see that the Examiner had relied on the alleged "mistake" in claim 1 when deciding to issue the '882 patent, and would thus not think that the alleged error was "manifest."

As is not uncommon, the Examiner provided a statement of his reasons for allowing the '882 patent to issue, which relied on the scope of application claim 23 as of June 22, 1997 — i.e.,

before it was broadened by Mr. Raffle's Certificate of Correction (DTX 306 at 222) (emphasis added):

The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose or suggest a method for applying energy to a target site on a patient body structure comprising providing an *electrode terminal* and a *return electrode* electrically coupled to a high frequency voltage source; positioning the *active electrode* in close proximity to the target site in the presence of an *electrically conducting terminal*; and, applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

As can be seen, the Examiner's Reasons for Allowance was clearly based on the "uncorrected" scope of application claim 23 as it essentially quotes that claim (compare the Reasons for Allowance with application claim 23 as set forth in the Amendment of March 25, 1997, DTX 306 at 201).

Moreover, anyone reviewing the file history would know that such a statement of Reasons for Allowance is binding on the patentee, absent an objection by the patentee. *See Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999) (holding that failure to respond to an examiner's reason for allowance functioned as a disavowal of a different interpretation of the claim). Thus, since ArthroCare never objected to the binding statement of Reasons for Allowance, there is simply no way that anyone reviewing the file history would think that it was "manifest" that there was an error in the statement, and thus in claim 1.

d. **The Alleged Errors Were Not Even "Manifest" To Mr. Raffle**

As shown above, claims 1 and 26 both included an "active electrode" as well as an "electrode terminal," and they both had antecedent basis problems. Mr. Raffle carefully reviewed both claims when the '882 patent issued. (DTX 306 at 235). Yet he only sought a Certificate of Correction with respect to claim 1, and he was perfectly happy to leave claim 26 alone (Tr. 1541) (D.L. 417):

Q. On the certificate of correction, you did not ask to change Claim 26; right?

A. I believe that's correct, yes. Claim 26.

- Q. As issued.
- A. As issued. That's correct.
- Q. You did not ask to correct that?
- A. That's correct.

Thus, to Mr. Raffle himself, the inclusion of both an "active electrode" and an "electrode terminal" in a claim was not a "manifest" error, and an antecedent basis problem with respect to one of those electrodes was also not a "manifest" error. Of course, as shown in Smith & Nephew's Opening Brief in Support of its Inequitable Conduct Case, Mr. Raffle's true motive in seeking the Certificate of Correction was to broaden claim 1 of the '882 patent for ArthroCare's lawsuit against Ethicon, and had nothing at all to do with correcting any actual "errors."

In light of this clear evidence, no reasonable juror could have found either the alleged errors in claim 1 of the '882 patent to be "manifest," or the manner of correcting those alleged errors to be "manifest." Accordingly, JMOL should be entered that the Certificate of Correction is not valid, and therefore that there is no infringement of the '882 patent by the accused Smith & Nephew products.

2. Non-suction Models of Smith & Nephew's Saphyre Products do Not Infringe Claim 54 of the '882 Patent Because ArthroCare Has Failed to Prove that these Products Satisfy the Requirement of "Evacuating Fluid Generated at the Target Site with a Suction Lumen Having a Distal End Adjacent the Electrode Terminal"

Claim 54 of the '882 patent requires evacuating fluid with a suction lumen having a distal end adjacent the electrode terminal. Several of the Saphyre models accused of infringing this claim do not come with suction. Thus, it is impossible for these models to evacuate fluid and infringe claim 54. ArthroCare has admitted that these products do not infringe this claim. D.I. 417 at 1493-94, D.I. 405 at 3. Thus, JMOL of non-infringement of claim 54 is appropriate with respect to these products.

G. Smith & Nephew Is Not Liable For Contributing To The Infringement Of Any Claim Of The Patents-In-Suit

Even if ArthroCare had offered evidence of direct infringement by Smith & Nephew customers, ArthroCare has not presented sufficient evidence from which a reasonable jury could find Smith & Nephew liable for contributory infringement under 35 U.S.C. § 271(c). As part of its case-in-chief on contributory infringement, ArthroCare had to prove that Smith & Nephew's probes are not staple articles of commerce suitable for substantial non-infringing uses. See 35 U.S.C. § 271(c). The focus of the analysis of non-infringing uses is the thing actually sold by the accused infringer. *Hodosh v. Block Drug Co.*, 833 F.2d 1575, 1578 (Fed. Cir. 1987). Yet ArthroCare never addressed the non-infringing uses, much less presented evidence that those uses are not substantial.

Indeed, Dr. Goldberg's only testimony on the contributory infringement or the non-infringing uses for Smith & Nephew's probes is:

Q. Now, Dr. Goldberg, the last subject I have for you today has to do with contributory infringement. Have you formed an opinion about whether Smith & Nephew is contributing to the infringement of ArthroCare's asserted claims through its sale of the Saphyre, the Control RF and the ElectroBlade?

A. Yes, I have.

Q. Tell us your opinion, please?

A. Smith & Nephew, by the fact that they are selling this device, teaching folks how to use it in an infringing way, are certainly contributing to the infringement of these patents.

Q. And can you tell us of any documents or other information on which you base your opinion?

A. Well, all the documents we have just gone through, the instructions for use and the sales guides, are clearly pointing, they are teaching to, and providing product to infringe these patents. *And an important point to add, in terms of the contributing to infringement, is that, as I have shown, the documents themselves say that they are selling these devices to be used for arthroscopic surgery, not for other things.*

(Tr. at 499-500) (emphasis added). Not only is this testimony not supported, but it is also facially misleading and prejudicial. As discussed above, the patents-in-suit are not limited to arthroscopic

devices and methods, and in fact are directed to open surgeries. ArthroCare's continual emphasis on arthroscopic products wrongly suggested to the jury that, since ArthroCare's *commercial* products are arthroscopic devices, Smith & Nephew's arthroscopic devices must infringe. This was unfair and misleading.

As described above, Dr. Goldberg's opinions that the use of Smith & Nephew's probes infringe the patents-in-suit lack sufficient factual support, ignore the Court's claim construction, and was not disclosed in Dr. Goldberg's expert report. Even if one accepts Dr. Goldberg's findings of infringement, it is readily apparent and uncontested that there are substantial non-infringing uses for the accused products that do not infringe the asserted claims of the patents-in-suit. In fact, there are numerous non-infringing uses for each of the accused products.

Examples of uses of the accused products that do not infringe the '592, '882, and '536 patent claims are using the probes to apply energy while the return electrode is in contact with tissue, using the probes to apply energy without creating a vapor layer, and using the probes as part of an electrosurgical system that does not have a fluid supply as part of a "unitary whole" electrosurgical system.

Dr. Goldberg has testified that the accused products infringe the claims of the '592 patent because in use they are *not always* in contact with tissue while energy is being applied. (Tr. at 421-22). In reaching this conclusion, Dr. Goldberg recognized that the return electrode of the accused devices does frequently touch tissue while power is being applied. (Tr. at 421-22) ("as the videotape and Mr. Marsden suggested, very clearly there is occasional contact frequently ..."). It is thus uncontested that using Smith & Nephew's probes to apply energy while the return electrode is in contact with tissue is a non-infringing use of these probes even under Dr. Goldberg's description of what constitutes infringement.

Absent some evidence that these the non-infringing uses of Smith & Nephew's probes (*i.e.*, use with the return electrode in contact with tissue) are not substantial non-infringing uses, no reasonable jury could conclude that Smith & Nephew is liable for contributory infringement.

H. Smith & Nephew is Not Liable for Inducement of Infringement of Any Claim of the Patents-in-Suit.

Nor has ArthroCare offered evidence sufficient to support a finding that Smith & Nephew has actively induced others to infringe any of the claims under 35 U.S.C. §271(b). To be liable for active inducement, the inducer must have "possessed the specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990). To prove inducement, ArthroCare bears the burden of proving first that Smith & Nephew's customers directly infringe, for there is no liability for inducement without a corresponding act of direct infringement. *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993); *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 604 F. Supp. 1485, 1487 (D. Del. 1985), *overruled on other grounds*, *National Presto Industries, Inc. v. West Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996) ("There can be no liability for inducement of infringement under section 271(b) unless an actual infringement in violation of section 271(a) is induced."). ArthroCare must also prove that Smith & Nephew induced that direct infringement. *Manville Sales*, 917 F.2d at 553. Additionally, ArthroCare must show that Smith & Nephew had actual intent to cause the acts which constitute the infringement *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468-69 (Fed. Cir. 1990).

ArthroCare offered no evidence that any customer of Smith & Nephew has ever used any one of the accused probes in a way that meets all of the limitations of any of the claims in suit. Indeed, the only evidence ArthroCare introduced about how Smith & Nephew customers use the products came from Smith & Nephew clinical evaluation surveys, which do not address most, much less all of the elements required by the claims. (D.L. 410 at 466, 471, and 484).

In addition, ArthroCare did not prove that Smith & Nephew *intends* to cause others to infringe any of the claims of the patents in suit. ArthroCare argued for the admissibility of otherwise inadmissible and highly prejudicial copying evidence, claiming that such evidence was relevant to show the intent to cause infringement element of its inducement charge. (Tr. at 24-

25). ArthroCare's "copying" story, which consisted only of an *ad hominem* attack and evidence that Smith & Nephew looked at certain ArthroCare products (with no evidence of actual copying), was wholly insufficient to show that Smith & Nephew actively induces any such infringement. Moreover, ArthroCare introduced no "evidence" of "copying" related to the Saphyre product.

ArthroCare also attempted to rely on evidence that Smith & Nephew instructs users to avoid contacting *non-target* tissue with the return electrode of the Saphyre product. (Tr. at 486). In arthroscopy, there is a well-recognized distinction between target and non-target tissue. Philip Eggers, one of the co-inventors of all three patents in suit, testified that tissue such as the meniscus is an example of target tissue and tissue such as cartilage is an example of non-target tissue. (Tr. at 351-352). Smith & Nephew does not instruct users to avoid contact with *any* tissue, it only instructs users to avoid contact with *non-targeted* tissue. Thus, ArthroCare's supposed evidence that Smith & Nephew is inducing infringement of the '592 patent claims by instructing surgeons not to contact non-targeted tissue with the Saphyre probe does not support Dr. Goldberg's conclusion, and, in fact, contradicts it.

ArthroCare's evidence is insufficient to support a finding that Smith & Nephew's customers or users actually use the accused probes in a way that directly infringes any of the claims, much less that Smith & Nephew actively induces them to do so.

L. Because The Relevant Factual Evidence Is Undisputed, This Court Should Find The Asserted Claims Of The Patents-In-Suit Invalid As A Matter Of Law

It is well recognized that a finding of invalidity requires proof by clear and convincing evidence. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996). Nonetheless, where the relevant facts are undisputed—whether the references are prior art and what those references disclose—a jury may not simply ignore those facts to find the patent valid. *See Verdegool Brothers, Inc. v. Union Oil Company Of California*, 814 F.2d 628, 632 (Fed. Cir. 1987) (granting JNOV based on the "uncontradicted disclosure" of a prior art reference); *see also IPPV Enterprises, LLC v. Echostar Communs. Corp.*, 191 F. Supp. 2d 530, 561-62 (D. Del. 2002)

(granting JMOL based on "undisputed evidence" that the patent was invalid as anticipated and finding that no reasonable jury viewing the documentary evidence . . . could fairly conclude otherwise"). If the prior art references show that all of the limitations of a patent claim are present, the trial court is *required* to enter JMOL of anticipation. See *id.*; *Anderson v. Liberty Lobby*, 477 U.S. 242, 250-51 (1986) ("The trial judge must direct a verdict if, under the governing law, there can be but one reasonable conclusion as to the verdict."); *Richardson-Vicks, Inc. v. Upjohn Co.*, Civ. Action No. 93-556-SLR, 1996 WL 31209 (D. Del.), *aff'd* 122 F.3d 1476 (Fed. Cir. 1997). (entering JMOL of invalidity where "the evidence, viewed in a light most favorable to plaintiff, nevertheless compels a verdict contrary to that of the jury").

1. There Are No Factual Disputes Relating To Validity

In the present case, there are *no* factual disputes relating to validity. First, there is no dispute that the six references relied on by Smith & Nephew are prior art. Moreover, there is no real dispute about the relevant disclosures of these references, or of the patents-in-suit.

Smith & Nephew proved by clear and convincing evidence that each of the asserted claims of the patents-in-suit is invalid. Its expert, Dr. Taylor, showed how—on a limitation-by-limitation basis—various prior art patents and articles anticipate the asserted claims of the '536 (D.I. 416 at 1294-1313), '882 (D.I. 416 at 1313-25) and '592 (D.I. 416 at 1325-34) patents. Similarly, Dr. Manwaring, one of Smith & Nephew's other experts, also showed that the '882 patent is invalid. (D.I. 414 at 883-96). ArthroCare, on the other hand, failed to put forth *any* evidence to rebut Smith & Nephew's *prima facie* showing of invalidity, and called no witnesses to testify on validity. Thus, ArthroCare failed to meet its burden to introduce rebuttal evidence showing that the claims are valid. *U.S. Environmental Prods. Inc. v. Westall*, 911 F.2d 713, 716 (Fed. Cir. 1990) (holding that once a defendant demonstrates a *prima facie* case of invalidity, the patent holder must come forward with convincing evidence to rebut the showing); *see also Hycor Corp. v. Schluter Co.*, 740 F.2d 1529, 1537 (Fed. Cir. 1984).

Instead, all ArthroCare did was cross-examine Smith & Nephew's experts. But ArthroCare's cross-examination fell far short of creating a record that can support the jury's

verdict that the asserted claims are valid. Nothing brought out in the cross-examinations of Drs. Taylor and Manwaring undermined the limitation-by-limitation analysis presented by these experts. ArthroCare's counsel merely cited irrelevant concessions related to claim construction arguments that ArthroCare had proposed, and that this Court had already rejected. In light of the verdict of validity, ArthroCare's focus on irrelevant cross-examination topics clearly confused the jury, since none of these "concessions" rebutted Smith & Nephew's clear and convincing evidence of invalidity. Thus, no reasonable jury could have failed to have found the patents invalid, and the jury's verdict cannot stand. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998).

2. The '536 Patent

Smith & Nephew proved by clear and convincing evidence that the asserted claims of the '536 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Elsässer and Roos Article (DTX 59A and 59B; D.I. 416 at 1294-1300), the Roos '198 patent (DTX 11; D.I. 416 at 1300-05), the Doss '007 patent (DTX 17; D.I. 416 at 1305-09), and the Pao '499 patent (DTX 21; D.I. 416 at 1309-13) each anticipate the asserted claims of the '536 patent. ArthroCare provided *no* rebuttal evidence to contradict Dr. Taylor's testimony, and instead relied on its cross-examination of Dr. Taylor to do nothing more than confuse the jury. However, Dr. Taylor did not waver or contradict his testimony during cross-examination, and his testimony did not provide ArthroCare with the rebuttal evidence it needed to overcome Smith & Nephew's *prima facie* case of invalidity.

a. The Pao '499 Patent

Perhaps the most obvious example of how ArthroCare confused and misled the jury, and of the jury ignoring the evidence with respect to the issue of invalidity involves the Pao '499 patent (DTX 21, Exhibit hereto). In his direct testimony, Dr. Taylor showed how the Pao '499 patent disclosed every limitation—on a limitation-by-limitation basis—in claims 46 and 56 of the '536 patent, as well as the unasserted independent claim 45 (D.I. 416 at 1309-13; Exhibit B).

In its cross-examination of Dr. Taylor relating to the Pao '499 patent (D.I. 416 at 1405-12), ArthroCare only asked him about one claim limitation—"the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue." But this is a limitation that is found *only* in claim 47 of the '536 patent (see JTX-1, claim 47 at col. 18, lines 32-36), which is the one claim against which Smith & Nephew did *not* assert the Pao '499 patent. (D.I. 416 at 1728). Thus, ArthroCare's cross-examination of Dr. Taylor on this issue was completely irrelevant and misleading.

Since ArthroCare did not offer any rebuttal evidence and did not even cross-examine Dr. Taylor with respect to any other claim term, it was *undisputed* at trial that the Pao '499 patent anticipates claims 45, 46, and 56 of the '536 patent. Yet the jury found otherwise. Thus, JMOL of invalidity of these claims *must* be entered. *Verdegoal Bros.*, 814 F.2d at 632; *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

b. The Doss '007 Patent

In his direct testimony, Dr. Taylor also showed how the Doss '007 patent (DTX 17, Exhibit 3) disclosed every limitation—on a limitation-by-limitation basis—of claims 45, 46, and 47 of the '536 patent. (D.I. 416 at 1305-09; Exhibit C). In its cross-examination of Dr. Taylor, ArthroCare asked him about only two claim limitations: "return electrode" and "connector located at the proximal end of the shaft." See JTX-1, claim 45 at col. 18, lines 18-22.¹² But once again ArthroCare failed to elicit any testimony that Smith & Nephew's invalidity case.

L. Return Electrode

Dr. Taylor explained that the Doss '007 patent discloses a return electrode under the Court's claim construction. (D.I. 416 1306-07, 1455-57). ArthroCare did not introduce any contrary testimony, and Dr. Taylor did not waver in his opinion on cross-examination. Instead of seeking any relevant testimony, ArthroCare asked a series of irrelevant and misleading questions regarding possible tissue effects by the return electrode. (D.I. 416 at 1380-99).

¹² These limitations are found in independent claim 45. "Since the patentee [] does not argue the validity of the dependent claims separately, their validity will stand or fall with the independent claim [45]." *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1480 (Fed. Cir. 1997).

First, ArthroCare asked Dr. Taylor whether the term "return electrode" was explicitly used in the Doss '007 patent. (D.I. 416 at 1380). ArthroCare was apparently trying to mislead the jury by suggesting that the words "return electrode" must be explicitly disclosed or the reference does not anticipate. This is clearly wrong, as claim limitations can be inherently found in a reference. *See MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999); *see also Tyler Refrigeration v. Kysa Ind. Corp.*, 777 F.2d 687, 689 (Fed. Cir. 1985). Thus, ArthroCare's attempt to show that an inherent limitation is not explicitly disclosed does not rebut Smith & Nephew's anticipation case. *MEHL/Biophile Int'l Corp.*, 192 F.3d at 1366; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

ArthroCare then set out on a path of questioning that not only ignored the Court's construction of the claim term "return electrode," but also reargued the claim construction that it had originally proposed and that the Court had rejected. ArthroCare had sought a claim construction that the return electrode would have minimal tissue effect. (Joint Claim Construction Statement) (D.I. 270 at 9). The Court squarely rejected ArthroCare's proposed claim construction, and instead held that "[a]s contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" (4/19/03 Memorandum Order at 4) (D.I. 353). Yet ArthroCare ignored the Court's claim construction, and attempted to mislead the jury by asking questions related to tissue effect by the return electrode. At this point in the trial, the Court expressed some concern that the question may be misleading "because it is maybe inconsistent with what I've said." (D.I. 416 at 1389). The Court went on:

THE COURT: Well, if you are saying there is no difference between the two, I mean I do believe that under this definition there has to be a difference between the active and the return. If you are saying and your point is that in the [Doss] prior-art reference there is no difference between the two, then that is an appropriate line of cross.

ArthroCare's counsel then assured the Court that that was his intention to show specifically that there was no difference between the two electrodes. (D.I. 416 at 1389-90). However, following this interchange, ArthroCare did not attempt to show that there is no

difference between the two, but instead went right back to asking about tissue effects (D.I. 416 at 1396):

Q. So again, my question, sir, simply is, is each electrode designed to cause a tissue effect?

A. Yes.

This line of questioning is clearly misleading as it fails to take into account the Court's claim construction, which permits the return electrode to have a tissue effect. Moreover, Dr. Taylor's answer in no way contradicts his prior testimony, nor his testimony on redirect (D.I. 416 at 1455-57) (emphasis added):

Q. Did you use the Court's definition of return electrode in determining whether or not the Doss reference had a return electrode?

A. Yes.

Q. And what is the critical element of the Court's definition of whether or not something constitutes a return electrode?

A. *The critical element is an electrode having a larger area of contact than an active electrode, thus affording a lower current density.*

Q. And when you reviewed the Doss patent, did you find such an electrode?

A. Yes. The outer electrode is -- just look at the geometry --

* * *

And just on the basis of plane geometry if you assume both electrodes have the same thickness, the outer electrode will have more surface area.

Q. And does that outer electrode meet the Court's definition of a return electrode?

A. I believe it does.

Thus, ArthroCare failed to rebut Dr. Taylor's clear and convincing testimony that the Doss '007 patent discloses a return electrode.

II. Connector Near the Proximal End of the Shaft

Dr. Taylor testified that the Doss '007 patent discloses a connector near the proximal end of the shaft (D.L. 416 at 1307), pointing specifically to col. 3, lines 30-34, which provides as follows:

Reference is made to Fig. 9 which schematically shows a two-electrode embodiment of the invention. A source of alternating voltage 12 such as a radio-frequency generator producing a 0.1 to 20 megahertz electric current is operably connected to electrodes 14 and 16.

This disclosure clearly meets this Court's interpretation of "connector" (4/9/03

Memorandum Order at 2) (D.L. 353):

The word connect means "to bind or fasten together; join or unite; link[.]" The word "connector," in terms of the '536 patent, shall be construed to mean a "structure that electrically links the electrode terminal to the high frequency power supply."

In its definition, the Court did not require that the connector be removable. Thus, a wire that passes through the proximal end of the device as shown in Figs. 7 and 9 of the Doss '007 patent would be a "connector" under the Court's construction.

However, in its cross-examination, ArthroCare once again ignored the Court's claim construction, and asked only whether the location of the connector was explicitly disclosed (D.L. 416 at 1400):

Q. And here in the Doss '007 patent, would you agree with me that there is no disclosure of where the connector is located, in other words, there is nothing that tells you where the connector is located with respect to the shaft?

A. Hold on a second. I believe that's correct. There is no specific mention of the location of that.

As discussed above, this is both misleading and legally incorrect because elements that are inherently disclosed still anticipate. Therefore, ArthroCare did not rebut Dr. Taylor's testimony that the Doss '007 patent discloses a connector near the proximal end of the shaft. *Verdegaal Bros.*, 818 F.2d at 631; *IPPV Enterprises, LLC*, 191 F. Supp. 2d at 561-62.

Because the return electrode and connector elements were the only ones that ArthroCare even attempted to demonstrate were not in the Doss '007 patent, and because ArthroCare patently

failed in that attempt, ArthroCare did not rebut Smith & Nephew's *prima facie* case that the claims 45, 46, and 47 of the '536 patent are invalid as anticipated by the Doss '007 patent and JMOL of invalidity should be entered based on this reference. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

c. The Elsässer and Roos Article and the Roos '198 Patent

In his direct testimony, Dr. Taylor showed how both the Elsässer and Roos Article (DTX 59A and 59B) and the Roos '198 patent (DTX 11, Exhibit 5) disclosed every limitation—on a limitation-by-limitation basis—of claims 45, 46, 47, and 56 (Ross '198) and 45, 46, and 56 (Elsässer and Roos Article) of the '536 patent (D.I. 416 at 1294-1305; Exhibits D and E). In its cross-examination of Dr. Taylor relating to these references, ArthroCare asked him only about two claim limitations—"electrically conducting fluid" and "connector near the proximal end of the shaft." See JTX-1, claim 45 at col. 18, lines 18-25. Again, the validity of the dependent claims, which ArthroCare did not separately challenge, stands or falls with the independent claim. *Richardson-Vicks*, 122 F.3d at 1480. And again, ArthroCare failed to rebut Smith & Nephew's clear and convincing invalidity proof.

i. Connector Near the Proximal End of the Shaft

ArthroCare cross-examined Dr. Taylor with respect to the "connector" limitation in the Roos '198 patent, but not with respect to the Elsässer and Roos Article. In any event, it was undisputed at trial that the Roos '198 patent and the Elsässer and Roos Article both disclose a connector at the proximal end of the shaft (DTX 11 at col. 7, lines 1-7) (emphasis added):

In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, *leading to the rear end of the endoscope* 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator...

Figure 7 and claim 1 further disclose a connector (DTX 11 at col. 7, lines 51):

Insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator...

Similarly, Figure 9 of the Elsässer and Roos Article clearly shows a removable connector near the proximal end of the endoscope. (DTX 59A at 133, Fig. 9) (Marsden Dec. Ex. 6)

It is clear that these disclosures in the Roos '198 patent and the Elsässer and Roos Article satisfy the limitation "connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply," as construed by the Court. First the Court held that the term "connector" simply means "a structure that electrically links the electrode terminal to the high frequency power supply." (4/9/03 Memorandum Order at 2) (D.L. 353). In its definition, the Court did not require that the connector be removable. Thus, a wire that passes through the proximal end of the device would be a connector under the Court's construction. The Roos '198 patent at Figure 7 and col. 7, lines 1-7 and the Elsässer and Roos Article at Figure 8 both show that all the wires lead to the rear (proximal end) of the endoscope. Thus, both references disclose a connector that is located at the proximal end of the shaft.

Second, Dr. Taylor testified that the Roos '198 patent and the Elsässer and Roos Article each disclose a connector near the proximal end of the shaft. (D.L. 416 at 1298 and 1302-03, respectively; *see also* Exhibits D and E). For example, Dr. Taylor explained how the Roos '198 patent discloses a connector at the proximal end of the shaft (D.L. 416 1301-03) (emphasis added):

Q. Have you done an element-by-element comparison of the teachings of the Roos '198 with the claims of the '536 patent?

A. Yes, I have.

• • •

A. ... A connector, requires a connector, coupling the shaft to the electrosurgical power supply. And that element is satisfied by Figure 7 and the text in Column 7, Lines 1 through 5. And also in Claim 1, as described here in this text. So that element is satisfied.

Dr. Taylor also explained that the disclosure of the connector in the Roos '198 patent was inherent (D.L. 416 at 1371-72):

A. You do realize that all resectoscopes have connectors at the back end of the resectoscope.

• • •

A. There is nothing in the '198 patent that says it explicitly. But there are no resectoscopes on the market that don't have a connector at the end, on the back of the resectoscope.

ArthroCare again did not introduce any contrary testimony and Dr. Taylor never wavered in his opinion. Instead, ArthroCare only asked whether the location of the connector was *explicitly* described in the Roos '198 patent (D.I. 416 1371). These questions were irrelevant since elements do not have to be explicitly recited to be found in a prior art reference. See *MEHL/Biophile*, 192 F.3d at 1365; *Tyler Refrigeration*, 777 F.2d at 687.

Further, ArthroCare did not present *any* evidence, not even through cross-examination, to contradict Dr. Taylor's testimony that the Elsässer and Roos Article discloses a connector at the proximal end of the shaft. And ArthroCare did not ask a single question about the connector's location in the Elsässer and Roos Article.

ii. Electrically Conducting Fluid

The other issue on which ArthroCare cross-examined Dr. Taylor related to the "electrically conducting fluid" limitation. Despite ArthroCare's lengthy cross-examination of Dr. Taylor, it was *undisputed* at trial that claim 1 of the Roos '198 patent and the Elsässer and Roos Article both explicitly disclose electrically conducting fluid. Claim 1 of the Roos '198 patent reads:

[A] space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with *liquid to provide electrical conductance* between said electrodes.

(DTX 11 at col. 7, lines 59-62) (emphasis added). Similarly, the Elsässer and Roos Article also explicitly discloses electrically conducting fluid:

[The device] offer[s] the high-frequency current a path to balance the potential difference that would be so short and *offer such a low resistance* that aberrant currents or leakage currents do not even occur... *The current flows directly from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid.*

(DTX 59B at 4) (emphasis added).

It is clear that the "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent and the "irrigation liquid" which "offer[s] such a low resistance" in the Elsässer and Roos Article are both the same as "electrically conductive fluid" as used in the '536 patent, for at least two reasons.

First, the words used in claim 1 of the Roos '198 patent and in the Elsässer and Roos Article both clearly meet this Court's interpretation of "electrically conductive fluid" (4/9/03 Memorandum Order at 3) (D.I. 353):

"[E]lectrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

In its definition, all the Court required was that the fluid "facilitate[] the passage of electrical current." Of course, a "liquid" is a type of "fluid," and since "facilitate" means simply "to make easier," a "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent squarely meets this Court's definition of "any fluid that facilitates the passage of electrical current." Similarly, the "irrigation liquid" that "offer[s] such a low resistance" would clearly "facilitate the passage of electrical current."

Second, the testimony at trial was *undisputed* that the Roos '198 patent and the Elsässer and Roos Article both disclose the use of electrically conducting fluid. Dr. Taylor testified that the Roos '198 patent and the Elsässer and Roos Article each disclose electrically conducting fluid. (D.I. 416 at 1299 and 1303, respectively). For example, Dr. Taylor explained that claim 1 of the Roos '198 patent explicitly discloses electrically conducting fluid (D.I. 416 at 1301-03) (emphasis added):

A. ... The Roos '198 patent basically follows up on the work that Doctors Elsässer and Roos did in their article and it's a bipolar electrosurgical device for the treatment of prostate and bladder tissue, commonly known as TURP.

* * *

It also requires an electrically conducting fluid supply, directed to the target site and generating current, flow path between the active and return electrode. That is diagrammatically shown here in Figures 7 and 8 and also specifically called out in Claim 1, basically the last line in Claim 1. So that element is satisfied.

Q. Just to pause on this one for a moment, that language that is quoted below the [demonstrative exhibit] drawing comes from Claim 1 of the Roos '198 patent?

A. That's correct.

Q. That is where you found support for the electrically conduct[ing] fluid limitation?

A. Yes.

ArthroCare did not introduce any contrary testimony, and did not call its own expert Dr. Goldberg to testify in rebuttal to Smith & Nephew's invalidity case. Dr. Taylor never changed his opinion. Instead, ArthroCare's strategy was to once again mislead the jury by having Dr. Taylor "admit" irrelevant facts that in no way contradicted or overcame the fact that these references disclose electrically conducting fluid.

For example, Dr. Taylor testified under cross-examination that the Roos '198 patent and the Elsässer and Roos Article do not use the words "saline" or "ringer's lactate." (D.I. 416 at 1375). However, this line of questioning was misleading since the asserted claims of the '536 patent do not require that the electrically conducting fluid be saline or ringer's lactate.¹³ Thus, ArthroCare failed to rebut Dr. Taylor's clear and convincing testimony that these references disclose an electrically conducting fluid under the Court's claim construction.

ArthroCare also questioned Dr. Taylor about how some other prior art monopolar TURP devices used glycine or other non-conductive fluids (D.I. 416 at 1339), apparently trying to suggest some connection between TURP procedures and non-conductive fluids.¹⁴ However, such a suggestion does not change the unchallenged fact that claim 1 of the Roos '198 patent explicitly discloses using electrically conducting fluid as Dr. Taylor testified.

ArthroCare also attempted to confuse the jury by pointing to embodiments in the Roos '198 patent that used contact between the return electrode and the tissue to provide some of the electrical connection. (D.I. 416 at 1345). However, Dr. Taylor pointed out that "this is not the embodiment that I talked about and it's not an embodiment that I described." (*Id.*). ArthroCare's focus on other embodiments is misleading. It is well-settled that all that is needed to anticipate is one anticipating embodiment or disclosure, even if other embodiments might not anticipate. *See*

¹³ The saline limitation is found only in asserted claims 11 and 32 of the '592 patent. The references Smith & Nephew relied upon for anticipation of the '592 patent, the Doss '007 patent and the Slager article, explicitly disclose saline.

¹⁴ The Roos '198 patent and Elsässer and Roos Article both describe devices that can be used in procedures other than TURP (DTX-11 at Col. 1, lines 18-22; DTX-59B at 5).

Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc., 127 F.3d 1065, 1068 (Fed. Cir. 1997) (holding that the district court erred in limiting the disclosure to the non-anticipating preferred embodiment when the other embodiments may anticipate). Therefore, this line of questions also did not rebut Dr. Taylor's direct testimony.

Finally, ArthroCare pointed to a later-issued patent, the Roos '667 patent. (PX-605) (Tr. at 1359-70). However, Dr. Taylor testified that the Roos '667 patent was irrelevant to his opinion that electrically conductive fluid was used in the Roos '198 patent (D.I. 416 at 1365-66) and ArthroCare adduced no evidence to the contrary.

None of Dr. Taylor's cross-examination testimony in any way contradicted his direct testimony, or the explicit disclosures of the references, that both the Roos '198 patent and the Elsässer and Roos Article clearly disclose an electrically conducting fluid. Thus, because ArthroCare put on no other evidence on this point, ArthroCare has not rebutted Smith & Nephew's *prima facie* case that the asserted claims of the '536 patent are invalid as anticipated by the Elsässer and Roos Article and the Roos '198 patent, and JMOL of invalidity of claims 46, 47, and 56 based on these references is clearly warranted. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

3. The '882 Patent

Smith & Nephew also proved by clear and convincing evidence that the asserted claims of the '882 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Manwaring '138 patent (DTX 46; D.I. 416 at 1313-17) anticipates claims 1, 13, and 54 and the Slager Article (DTX 65; D.I. 416 at 1317-20) anticipates claims 1, 13, 17, and 54 of the '882 patent. Dr. Manwaring, one of Smith & Nephew's other experts, also testified that the Manwaring '138 patent anticipated claims 1, 13, and 54 of the '882 patent. (D.I. 416 at 886-96). Dr. Taylor further testified that the asserted claims are invalid as not enabled under 35 U.S.C. § 112, because the supposed new process of "coblation" is not adequately described to differentiate it from the prior art. (D.I. 416 at 1320-25).

ArthroCare once again provided no rebuttal evidence to contradict Dr. Taylor's and Dr. Manwaring's testimony, and instead relied on its cross-examination of these experts to confuse and mislead the jury. However, neither Dr. Taylor nor Dr. Manwaring wavered or contradicted their testimony during cross-examination, and their testimony went un rebutted.

a. The Slager Article

In its cross-examination of Dr. Taylor relating to the Slager Article (DTX 65), ArthroCare asked about two claim limitations—"at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum" and "evacuating fluid generated at the target site"; as well as a portion of the preamble to claim 1 of the '882 patent—"applying energy to a target site on a patient body structure." However, ArthroCare failed to rebut Smith & Nephew's *prima facie* case of invalidity of the '882 patent.

L UV Photons

Dr. Taylor testified that the Slager Article discloses energy in the form of photons having a wavelength in the ultraviolet spectrum (UV photons), which is a limitation in claim 13. (D.I. 416 at 1319; Exhibit F). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to mislead the jury by suggesting that, because UV photons were not explicitly disclosed, UV photons were not present at all. (D.I. 416 at 1419-21).

However, Dr. Taylor explained, in detail, why the production of UV photons is inherently disclosed in the Slager Article based on principles of elementary chemistry:

Q. So just from seeing a spark, just from seeing that flash of light with the naked eye, you can't tell whether or not there is ultraviolet light in there or whether there isn't. True?

A. That's true, except you can't have a spark in aqueous solution without the UV light.

* * *

Q. So you didn't do any tests and you didn't look at the literature; correct?

A. Right. One has to realize, though, that if you have a spark in an aqueous solution, especially a sodium chloride aqueous solution, that you will generate UV photons because of the transition of the hydroxyl ion. You will

also generate what we would consider to be orange, yellowish-orange light, 580 nanometers, because of the sodium ion transition. That is college chemistry.
(D.I. 416 at 1419-20) (emphasis added).

Dr. Taylor's testimony that the Slager Article inherently discloses the production of UV photons was not rebutted by ArthroCare, and therefore, for purposes of anticipation analysis, it does contain that limitation. *See generally Verdegaal Brothers*, 814 F.2d at 631 (holding that a patent claim is anticipated by a reference that either explicitly or inherently discloses all of the claim limitations).

ii. Evacuating Fluid Generated at the Target Site

Dr. Taylor also testified that the Slager Article discloses evacuating fluid (bubbles) generated at the target site, which is a limitation in claim 54. (D.I. 416 at 1320; Exhibit F). ArthroCare did not introduce any contrary testimony and Dr. Taylor never wavered on cross-examination. Instead, ArthroCare again attempted to mislead the jury by suggesting that, because the exact suction technique was not explicitly disclosed, that a suction lumen adjacent the electrode terminal is not disclosed. (D.I. 416 at 1425-26).

iii. Applying Energy to a Patient Body Structure

Dr. Taylor testified that the Slager Article anticipates claim 1 of the '882 patent. (Tr. at 1319; Exhibit F). Again, ArthroCare did not introduce any contrary testimony and instead attempted to mislead the jury by suggesting that, because the tissue used by Slager was a piece of aorta in a lab dish, the Slager Article did not disclose a "method for applying energy to a target site on a patient body structure" as set forth in the preamble of the '882 patent. (Tr. at 1426-28).

The reference to "patient body structure" merely sets forth the intended environment of use in the preamble of the claim, and does not constitute a claim limitation. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346-47 (Fed. Cir. 2002); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1373-75 (Fed. Cir. 2001).

Moreover, ArthroCare's suggestion is completely undercut by the position it took with respect to conception and reduction to practice of claim 1 of the '882 patent. In particular, in

order to avoid some of Smith & Nephew's prior art, ArthroCare asserted that claim 1 of the '882 patent was reduced to practice by June 18, 1993. (DTX 406). However, Philip Eggers, one of the inventors of the patents-in-suit, testified that as of 1993 his experiments had not progressed to being used in live patients, but only involved chicken parts in bowls of saline (D.I. 410 at 295):

Q. My question to you, Mr. Eggers, is: As of January 25, 1993, or February 8, 1993, the development of your invention had not progressed to the point that it was being used on actual patients; right?

A. That's correct.

Q. It was only being used in experiments in bowls of saline on various chicken parts; right?

A. Correct.

Thus, the inventor himself believed that experiments in bowls of saline were covered by methods of applying energy to a target site on a body structure.¹⁵ ArthroCare cannot have it both ways. If experiments on chicken parts in bowls of saline were sufficient to constitute reduction to practice of a "method for applying energy to a target site on a patient body structure," then a prior art method involving human aorta tissue in a lab dish certainly must also qualify as such a method. Accordingly, ArthroCare did not rebut Dr. Taylor's testimony, nor did it contradict his conclusion that the Slager Article anticipates the asserted claims of the '882 patent.

Therefore, ArthroCare failed to rebut Smith & Nephew's *prima facie* case of invalidity based on the Slager Article, and JMOL of invalidity of claims 13, 17, and 54 based on this reference is warranted. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

b. The Manwaring '138 Patent

In its cross-examination of Dr. Taylor relating to the Manwaring '138 patent (DTX 46), ArthroCare asked him about two claim limitations—"at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum" and "evacuating fluid generated at the target site." ArthroCare also asked about these same two limitations in its cross-

¹⁵ Claim 1 of the '882 patent was reduced to practice in June 1993, and there is no evidence that the invention progressed to use in live patients in that time. Further, the language in the '592

examination of Dr. Manwaring. However, ArthroCare failed to rebut Smith & Nephew's invalidity case in either cross-examination, and did not introduce any rebuttal evidence of its own.

I. UV Photons

Dr. Taylor testified that the Manwaring '138 patent discloses UV photons. (D.I. 416 at 1316; Exhibits G and H). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to mislead the jury by suggesting that, because Dr. Taylor did not test for UV photons, UV photons were not present at all. (D.I. 416 at 1429). However, as discussed above, Dr. Taylor explained why UV photons are inherently present when you have sparking in an aqueous solution, such as the sparking found in the Manwaring '138 patent, as a matter of elementary chemistry. (See D.I. 416 at 1316 and DTX 46 at col. 6, lines 50-63).

Dr. Taylor's opinion was corroborated by Dr. Manwaring. (D.I. 414 at 893-95 and 917-19). ArthroCare did not introduce any contrary testimony and Dr. Manwaring also never wavered on cross-examination. Instead, ArthroCare attempted to mislead the jury by suggesting that, because UV photons were not explicitly disclosed, UV photons were not present at all. (D.I. 414 at 897-98). But making such a suggestion does not satisfy ArthroCare's obligation to introduce evidence relating to validity. *Verdegoal Bros.*, 814 F.2d at 631; *IPPV Enterprises, LLC*, 191 F. Supp. 2d at 561-62.

Thus, ArthroCare failed to rebut the testimony of either Dr. Taylor or Dr. Manwaring regarding the inherent presence of UV photons.

II. Evacuating Fluid Generated at the Target Site

Dr. Taylor testified that the Manwaring '138 patent discloses evacuating fluid generated at the target site. (D.I. 416 at 1316-17; Exhibits G and H). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to obfuscate the issues and mislead the jury by suggesting an improper limitations to this claim.

patent, which was reduced to practice in February 1993, includes almost identical language: "method for applying energy to a target site on a body structure on or within a patient's body."

First, ArthroCare attempted to mislead the jury by suggesting that *all* of the fluid at the target site must be evacuated (D.I. 416 at 1432-33) (emphasis added):

Q. Right. But you are not going to take the fluid from this region at the tip and suck *all of the fluid way over here, way up into the device and leave no fluid down at the tip*, are you? You're going to suck fluid in, so that electrode tip has some fluid in contact with it; right?

A. Oh, yes.

ArthroCare asked similarly misleading questions of Dr. Manwaring during his cross-examination (D.I. 414 at 904-05):

Q. So isn't it fair to say, then, that [sic] fluid remains at or on the target site, that you are trying to treat in the course of a surgery?

A. That's correct.

This was clearly misleading because there is no requirement that *all of the fluid* be evacuated. (See JTX-2 at claim 54 and col. 23, lines 24-33). ArthroCare's misleading suggestion does not overcome Dr. Taylor's and Dr. Manwaring's testimony that the Manwaring '138 patent discloses evacuation.

Second, ArthroCare tried to suggest that what is evacuated is not fluid generated at the target site, but rather the electrically conducting fluid (D.I. 414 at 903-04). This suggestion is irrelevant and misleading because, as Dr. Manwaring explained, the lumen would evacuate a mixture including saline as well as fluid that was generated at the target site (D.I. 414 at 921-21):

Q. Would there be some fluid that was removed from the target site?

A. Yes. Fluid would always be there, and the evacuation, whether it is sucking, essentially pulls fluid which is salt laden, electrically conductive, by the electrode. That's the principle.

Q. Do you consider that evacuation?

A. Yes.

Q. Now, the fluid that is evacuated, would that include fluid that was generated at the target site?

A. It can.

Q. What kind of fluid would that include?

A. Well, heating in the presence of biologic tissue. Let's say one is ablating, which means removing, tumor tissue in the brain. That tissue is vaporized. And in that vaporization is fluid in the form of gas, which quickly mingles with the spinal fluid or the irrigated normal saline. So it's a mix again.

This is consistent with the explicit disclosure of the '882 patent. (JTX-2 at col. 23, lines 30-34). Thus, ArthroCare failed to rebut the testimony of either Dr. Taylor or Dr. Manwaring regarding the evacuation of fluid generated at the target site.

Therefore, ArthroCare failed to rebut Smith & Nephew's *prima facie* case of invalidity of the asserted claims based on the Manwaring '138 patent and the Court should enter JMOL that claims 13, 17, and 54 are anticipated. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

c. Enablement

Dr. Taylor also testified that the '882 patent is invalid for lack of enablement. (D.L. 416 at 1320-25). The test for whether patent claims are enabled is whether the specification teaches those of ordinary skill in the art how to make and use the full scope of the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

The specification explains that the process of the '882 results in phenomenon the inventors called "cold ablation," which "can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells." '882 patent at 11:38-41.

The specification itself essentially establishes the enablement problem:

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors.

Id. at 11:4-13. The specification further explains that the ionization induces the discharge of energetic electrons only "under optimal conditions." *Id.* at 10:65-66.

Despite this requirement of "optimal" conditions, the specification fails to specify what particular parameters should be used. Instead, the specification gives large ranges of parameters for nine different variables, with no guidance as to what particular combinations would result in the "optimal conditions" required for cold ablation.

Despite using this term in the patent, the evidence showed that ArthroCare itself recognized that the method of operation of its invention is not new at all, but identical to the prior art. ArthroCare has frequently backed off of this "cold ablation" assertion. Specifically, as Dr. Taylor explained, the principle of operation of the System 970, which ArthroCare asserts is covered by the patents-in-suit Tr. 1505 is the same as how prior art devices work (D.I. 416 at 1323) (emphasis added):

Q. Do you have any opinion as to whether ArthroCare's description of the mode of operation or the principle of operation of its System 970 is consistent with the opinion that you have offered here in court in this morning?

A. Yes. Essentially, the opinion that I have, I think what is confirmed here in the text, is that *the system operates in the same manner as a conventional electrosurgical system, use of arcing and such, that is described by what is known as prior art*, stuff that has been known for a long time.

With this understanding, and admission that the allegedly patented devices operate like prior art electrosurgical devices, Dr. Taylor, who was clearly qualified as one of skill in the art [cite], testified that if ArthroCare tried to distinguish its patents over the prior art based on its alleged "Coblation" phenomenon, the claims would not be enabled (D.I. 416 at 1324-25):

Q. Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?

A. Yes, I have an opinion.

Q. What is that opinion?

A. That it is not.

On cross-examination, Dr. Taylor did not contradict this testimony. ArthroCare's counsel merely cross-examined him on a laundry list of preferred embodiment parameters that were included in the '882 patent. (D.I. 416 at 1436-38). However, this did not rebut Dr. Taylor's testimony in any way. None of these preferred embodiment parameters discloses how one skilled

in the art duplicating the device would get a device that produces "Coblation" instead of the prior art arcing described in ArthroCare's principle of operation.

Further, if one were to build a device within the preferred embodiment parameters of the '882 patent, the result would simply be the device of the prior art Manwaring '138 patent. Here is a comparison of the most preferred embodiment of the '882 patent to the disclosure in the Manwaring '138 patent:

Preferred element	'882 Patent	The Manwaring '138 Patent
Active electrode surface area	1 to 20 mm ² (15:37-39)	1.4 mm ² (5:20-27)
Active electrode spaced from tissue	0.05 to 0.5 mm (15:63-66)	0 to 2 mm (5:55-61 and 6:53-57)
Active electrode may be flush with probe surface	(16:55-56)	(5:55-61)
Active electrode may be recessed from surface	0.01 to 0.2 mm (16:57-60)	0 to 2 mm (5:55-61)
Active electrode may be several materials	platinum, titanium tantalum or tungsten (16:64-66)	stainless steel or tungsten (5:20-21)
Fluid is preferably saline	(12:38-40)	(7:6-8)

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case of invalidity based on non-enablement, and the Court should enter JMOL. See generally, *Enzo Biochem., Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999) (finding that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure" and that "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention").

4. The '592 Patent

Smith & Nephew also proved by clear and convincing evidence that the asserted claims of the '592 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Doss '007 patent (DTX 17; D.I. 416 at 1325-30; Exhibit I) and Slager Article (DTX 65; D.I. 416 at 1330-34; Exhibit J) each anticipate the asserted claims of the '592 patent. ArthroCare again provided no rebuttal evidence to contradict Dr. Taylor's testimony, and instead

relied on its cross-examination of Dr. Taylor to confuse and mislead the jury. However, Dr. Taylor did not withdraw or contradict his testimony during cross-examination.

a. Doss '007

In its cross-examination of Dr. Taylor relating to the Doss '007 patent (DTX 17), ArthroCare asked about only two claim limitations—"return electrode" and "voltage [] in the range from 500 to 1400 volts peak to peak." See, e.g., JTX-3, claims 1 and 21. But once again ArthroCare failed to elicit any testimony to rebut Smith & Nephew's invalidity case.

I. Return Electrode

The '592 patent contains the same "return electrode" limitation as the '536 patent, discussed above at Section 2(b)(i). And as with the '536 patent, ArthroCare did not rebut Dr. Taylor's testimony that the Doss '007 patent discloses a return electrode. Further, this limitation is found in independent claim 1. Since ArthroCare did not argue the validity of claims 3, 4, or 11 separately, their validity will stand or fall with independent claim 1. *Richardson-Vicks*, 122 F.3d at 1480.

II. Voltage in the Range From 500 to 1400 Volts

Dr. Taylor testified that the Doss '007 patent inherently discloses a voltage in the range from 500 volts to 1400 volts peak to peak. (D.I. 416 at 1330). ArthroCare put on no evidence to rebut this testimony. Instead, ArthroCare once again limited its cross-examination to simply showing that the limitation was not expressly disclosed, ignoring the settled law that a limitation can be present in anticipating prior art inherently. *MEHL/Biophlle*, 192 F.2d at 1365.

As explained by Dr. Taylor, instead of disclosing the peak to peak voltage, the Doss '007 patent discloses a voltage of 20 to 200 volts RMS (root-mean-square). To convert from voltage expressed in RMS, one needs to multiply by 2.83 to get voltage expressed in peak-to-peak units. (D.I. 416 at 1330). This conversion results in a voltage of 560 volts peak-to-peak for the Doss '007 patent. (*Id.*). ArthroCare attempted to confuse the jury regarding this inherent disclosure by

asking Dr. Taylor whether the Doss '007 patent expressly disclosed a sine wave, which is the most common waveform used. (D.I. 416 at 1402). Dr. Taylor maintained his opinion (*id.*):

Q. And there is nothing in the Doss patent that says that a sine wave is used with this generator; correct?

A. That's correct.

Q. So we don't know whether there is a sine wave here or a square wave or some other waveform; right?

A. You're correct. But, to my knowledge, there are no commercially-available square wave generators.

Thus, ArthroCare failed to rebut Dr. Taylor's testimony that the Doss '007 patent inherently discloses a voltage of from 500 to 1400 volts peak-to-peak.

Therefore, ArthroCare has not rebutted Smith & Nephew's *prima facie* case that the asserted claims of the '536 patent are invalid as anticipated by the Doss '007 patent, and JMOL based on this reference is clearly warranted. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

b. Slager Article

In its cross-examination of Dr. Taylor relating to the Slager Article (DTX 65), ArthroCare asked only about one claim limitation—"spacing a return electrode away from the body structure in the presence of the electrically conductive fluid"; and the preamble language—"applying electrical energy to a target site on a body structure on or within a patient's body." See JTX-3 at claim 23. ArthroCare again failed to elicit testimony sufficient to rebut Smith & Nephew's invalidity case. Further, this limitation is found in independent claim 23. Since ArthroCare did not argue the validity of claims 26, 27, 32, or 42 separately, their validity will stand or fall with independent claim 1. *Richardson-Vicks*, 122 F.3d at 1480

1. Applying Energy to a Target Site on a Body Structure on or Within a Patient's Body

The '592 patent contains the same "on or within a patient's body" limitation as the '882 patent. And as discussed above with respect to the '882 patent in Section F(3)(a)(iii), ArthroCare

did not rebut Dr. Taylor's testimony that the Slager Article discloses a method for applying energy to a target site on a body structure on or within a patient's body.

**II. Spacing a Return Electrode Away from the Body Structure
in the Presence of the Electrically Conductive Fluid**

The Slager Article expressly discloses that a section of aortic tissue approximately 4 by 7 centimeters in size was used in an *in vitro* experiment. (DTX 65 at 1382.) The article also discloses that the spacing between the active electrode and return electrode varied between 2 to 10 centimeters. (*Id.* at 1383.) Thus, when the distance between the electrodes was 7 centimeters or more, the return electrode was necessarily not touching the aortic tissue sample. Dr. Taylor testified that the Slager Article discloses spacing a return electrode away from the body structure in the presence of the electrically conductive fluid. (D.I. 416 at 1331). ArthroCare did not introduce any testimony to the contrary. Instead, ArthroCare asked Dr. Taylor a series of misleading cross-examination questions regarding an experiment described in the Slager Article on which Dr. Taylor was *not* basing his testimony.

Specifically, the Slager Article describes both an *in vitro* and an *in vivo* experiment. (See DTX 65). These are two different experiments. Dr. Taylor based his opinion of invalidity on the *in vitro* experiment. His testimony on this point could not have been clearer. (D.I. 416 at 1414):

Q. And the portions of this article that you were saying were relevant to the '882 and the '592 patent related to the *in vitro* test; correct? Not to the test on the pig?

A. You said the *in vitro* test?

Q. I did.

A. Yes.

Q. Okay. The *in vitro* means what in this article?

A. *In vitro* means it's outside the body, generally in a dish preparation of some sort. I guess it's the opposite of *in vivo*, which is inside the body.

ArthroCare's counsel nevertheless went on to ask misleading questions about the irrelevant *in vivo* experiment, which did not form any part of the basis for Dr. Taylor's testimony (D.I. 416 at 1416-18). The jury may have been misled to believe that because the *in vivo*

experiment did not disclose all of the limitations, the same is true for the *in vitro* test. While the jury may have been misled, this cross examination did not rebut Dr. Taylor's clear testimony that the *in vitro* test in the Slager Article discloses a return electrode spaced away from the body structure in the presence of the electrically conductive fluid, nor does it rebut the explicit disclosure of the Slager Article. See *Ultradent Prods.*, 127 F.3d at 1068 (a reference anticipates if any one embodiment anticipates, even if other embodiments do not).

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case that the asserted claims of the '592 patent are invalid as anticipated by the Slager Article, and JMOL is warranted based on this reference. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

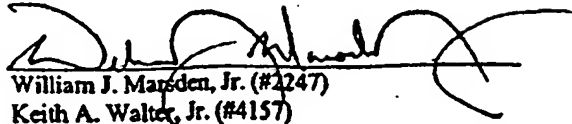
V. CONCLUSION

For the foregoing reasons, Smith & Nephew respectfully requests that the Court enter Judgment as a Matter of Law that the '882 certificate of correction is invalid, that the accused products do not infringe the asserted claims, that the asserted claims of the '536 and '592 patent are anticipated by the prior art, and that the asserted claims of the '882 patent are not enabled and are anticipated by the prior art.

Dated: June 30, 2003

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CERTIFICATE OF SERVICE

I hereby certify that on this 30TH day of June, 2003, a true and correct copy of SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW was caused to be served on the attorneys of record at the following addresses as indicated:

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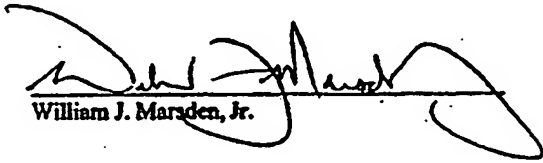
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A 17163

Anticipation by The Pao '499 Patent
DTX-21

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electro-surgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	"The court shall apply the ordinary definition of the term 'system.' The term 'system' shall be construed to mean 'an assemblage or combination of things or parts forming a unitary whole.'" D.I. 353 at 5.	The Pao '499 abstract generally describes the Pao invention as an electro-surgical device used in electrocautery and electrocoagulation operations. See also, Col. 1, lines 15-18 and Claim 1. All of the components, including the fluid supply, are combined as a unitary whole in the probe.	ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met the preamble at trial.
a high frequency power supply;	The Court did not construe this limitation.	Dr. Taylor's testimony at Tr. 1310 Pao '499 discloses a high frequency bipolar power supply throughout. See, e.g., col. 7, lines 35-36.	ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.
an electro-surgical probe comprising a shaft having a proximal end and a distal end,	"The term 'distal end' shall be construed to mean 'the end situated away from the point of origin or attachment.' The term 'proximal end' shall be construed to mean 'the end situated towards the point of origin or attachment.'" D.I. 353 at 5.	Dr. Taylor's testimony at Tr. 1310-11. Pao '499 discloses an electrode assembly portion (shaft) having a terminal region (distal end) and a proximal end. See col. 7, lines 6-9; col. 7, lines 13-30; see also Fig. 7, which generally shows a distal end and proximal end.	ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.
		Dr. Taylor's testimony at Tr. 1311.	

Anticipation by The Pao '499 Patent
DTX-21

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an electrode terminal disposed near the distal end, and	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" <i>Id.</i></p>	<p>Pao '499 discloses an axial electrode (electrode terminal consisting of a single active electrode) at the terminal region (distal) end of the electrode assembly (shaft). See, e.g., col. 7, lines 15-19; see also Fig. 9, which generally shows the axial electrode 236 (electrode terminal) at the terminal region 232 (distal) end of the electrode assembly 212 (shaft).</p> <p>Dr. Taylor's testimony at Tr. 1311.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.</p>
a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;	<p>"The word connect means 'to bind or fasten together, join or unite; link[.]' The word 'connector,' in terms of the '536 patent, shall be construed to mean 'a structure that electrically links the electrode terminal to the high frequency power supply.'" D.I. 353 at 2.</p>	<p>Pao '499 discloses an electrical connection portion 220 (connector) near the proximal end of the shaft, which couples the axial electrode (electrode terminal) to the high frequency power supply. See, e.g., col. 7, lines 25-37; col. 6, lines 8-13; see also Figs. 7, which shows the pins at the proximal end.</p> <p>Dr. Taylor's testimony at Tr. 1311.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.</p>

Anticipation by The Pao '499 Patent
DTX-21

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
a return electrode electrically coupled to the electrosurgical power supply; and	"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.	Pao '499 discloses an outer electrode (return electrode) at the terminal region (distal end), which is electrically coupled to the high frequency generator by the pins and female connector. See, e.g., col. 7, lines 13-19; col. 7, lines 25-37; col. 6, lines 8-13. The outer electrode has a larger area of contact than the axial (active) electrode. Dr. Taylor's testimony at Tr. 1311.	ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.

Anticipation by The Pao '499 Patent
DTX-21

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.	<p>"Consistent with the prosecution history, the phrase 'electrically conducting fluid supply' shall be construed to mean 'a medical container that stores electrically conducting fluid.' ... An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline." D.I. 353 at 2.</p> <p>"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conducting fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." <i>Id.</i> at 3.</p> <p>Directing or delivering the electrically conductive fluid to the target site "shall be construed consistent with its ordinary meaning; no further construction is necessary." <i>Id.</i> at 3.</p>	<p>Pao '499 discloses a central lumen 260 in the axial electrode (electrode terminal) that is coupled to an electrically conducting fluid supply, such as a bottle or bag of saline solution, which will direct the saline to the target site to generate a current flow path between the outer electrode (return electrode) and the axial electrode (electrode terminal). See col. 7, lines 21-25; col. 7, lines 63-67; col. 8, lines 34-49.</p> <p>Dr. Taylor's testimony at Tr. 1311-12.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.</p>

Anticipation by The Pao '499 Patent
DTX-21

Claim 46 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electro-surgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electro-surgical probe.		Pao '499 discloses all the limitations of claim 45 as show above.	See above.
	The Court did not construe this limitation.	Pao '499 discloses that the outer electrode 228 (i.e., the return electrode) forms a portion of the probe (shaft) region. Col. 2, lines 58-60, see Figs. 7 and 9. Dr. Taylor's testimony at Tr. 1312.	ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.

Claim 56 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
The electro-surgical system of claim 45 wherein the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.		Pao '499 discloses all the limitations of claim 45 as show above.	See above.
	The Court did not construe this limitation.	Target sites described in this reference include the nose and ears. Col. 9, lines 37-42. Dr. Taylor's testimony at Tr. 1312-13.	ArthroCare did not offer any rebuttal evidence or dispute that Pao '499 met this limitation at trial.

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A 17169

**Anticipation by the Manwaring '138 Patent
DTX-46**

Claim 1 of the '882' Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
A method for applying energy to a target site on a patient body structure comprising: providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" <i>Id.</i></p> <p>"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.</p>	<p>Manwaring '138 generally describes applying RF energy to tissue for endoscopic procedures. Col. 1, lines 7-9.</p> <p>Dr. Taylor's testimony at Tr. 1314-15</p> <p>Manwaring '138 discloses a conductor 34 with a second end 36 (electrode terminal) within recessed cylinder chamber 38 and a first end coupled to the RF generator. Col. 5, lines 37-43. A return electrode is located on the patient and connected to the RF generator. Col. 6, lines 38-40.</p> <p>Dr. Taylor's testimony at Tr. 1314-15</p> <p>Dr. Manwaring's testimony at Tr. 889-90</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that the Manwaring '138 patent met the preamble at trial.</p> <p>ArthroCare did not offer any rebuttal evidence or dispute that the Manwaring '138 patent met this limitation at trial.</p>

¹ For this analysis only, Smith & Nephew will assume that the Certificate of Correction is valid.

Anticipation by the Manwaring '138 Patent
DTX-46

Claim 1 of the '882' Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and	"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.	To the extent this claim can be understood and the Certificate of Correction is found to be valid, Manwaring '138 discloses positioning the active electrode 36 in close proximity to the target tissue in the presence of saline. Col. 6, lines 3-8, 53-57 and 64-68. Dr. Taylor's testimony at Tr. 1314-15 Dr. Manwaring's testimony at Tr. 890-91	ArthroCare did not offer any rebuttal evidence or dispute that the Manwaring '138 patent met this limitation at trial.
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.	The Court did not construe this limitation.	Manwaring '138 discloses applying RF energy to create a spark which vaporizes the saline within the region 46 adjacent the active electrode. Col. 6, lines 50-63; Fig. 5 Dr. Taylor's testimony at Tr. 1314-15 Dr. Manwaring's testimony at Tr. 891-93	ArthroCare did not offer any rebuttal evidence or dispute that the Manwaring '138 patent met this limitation at trial.

Anticipation by the Manwaring '138 Patent
DTX-46

Claim 13 of the '882 The method of claim 1 wherein	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.	The Court did not construe this limitation.	Manwaring '138 discloses all the limitations of Claim 1 as show above. Manwaring '138 specifically mentions sparking during operation. Column 6, lines 50-63. The spark in an aqueous solution, such as saline, results in the emission of UV photons and other wavelengths of light. Dr. Taylor's testimony at Tr. 1316 Dr. Manwaring's testimony at Tr. 893-94 and 917-19.	See above. ArthroCare did not offer any rebuttal evidence. However, ArthroCare did cross-examine Drs. Taylor and Manwaring with respect to whether the Manwaring '138 patent explicitly discloses the production of photons having a wavelength in the ultraviolet spectrum (UV photons). However, both Drs. agreed that the production of UV photons is inherent when sparking occurs in an aqueous solution. See, Tr. 1419-20 (Dr. Taylor) and Tr. 918-19 (Dr. Manwaring).

Claim 54 of the '882 The method of claims 23 or 48 further comprising	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.	The Court did not construe this limitation.	Manwaring '138 discloses all the limitations of Claim 1 and 28 as show above. Manwaring '138 discloses evacuating fluid generated at the target site using a suction lumen with a distal end adjacent the electrode terminal. Col. 7, lines 26-31.	See above. ArthroCare did not offer any rebuttal evidence. ArthroCare did cross-examine Drs. Taylor and Manwaring

Anticipation by the Manwaring '138 Patent
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Claim 54 of the '882	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position with respect to whether the Manwaring '138 patent discloses evacuating the fluid generated at the target site.
		<p>Dr. Taylor's testimony at Tr. 1316-17.</p> <p>Dr. Manwaring's testimony at Tr. 895-96; see also 920-21:</p> <p>Q. Would there be some fluid that was removed from the target site?</p> <p>A. Yes. Fluid would always be there, and the evacuation, whether it is sucking, essentially pulls fluid which is salt laden, electrically conductive, by the electrode. That's the principle.</p> <p style="text-align: center;">* * *</p> <p>Q. Now, the fluid that is evacuated, would that include fluid that was generated at the target site?</p> <p>A. It can.</p> <p>Q. What kind of fluid would that include?</p> <p>A. Well, heating in the presence of biologic tissue. Let's say one is ablating, which means removing, tumor tissue in the brain. That tissue is vaporized. And in that vaporization is fluid in the form of gas, which quickly mingles with the spinal fluid or the irrigated normal saline. So it's a mix again.</p>	<p>However, ArthroCare's misleading and irrelevant questions focused on whether all the fluid was evacuated (Tr. 1432-33) and whether it was the electrically conducting fluid being evacuated (Tr. 903-05).</p> <p>First, there is no requirement that <i>all</i> the fluid be evacuated from the target site. Second, Dr. Manwaring made it quite clear that a mixture of fluid generated at the target site (e.g. gases) and electrically conductive fluid would be evacuated from the target site (Tr. 921-22). Thus, ArthroCare did not rebut Smith & Nephew's <i>prima facie</i> showing of invalidity.</p>

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A 17174

Anticipation by The Doss '007 Patent
DTX-17

Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	"The court shall apply the ordinary definition of the term 'system.' The term 'system' shall be construed to mean 'an assemblage or combination of things or parts forming a unitary whole.'" D.I. 353 at 5.	Doss '007 describes a bipolar probe, used to apply RF energy to target tissue. See the Abstract; see also col. 1, lines 10-13; col. 2, lines 42-54. All of the components, including the fluid supply, are combined as a unitary whole in the probe. Dr. Taylor's testimony at Tr. 1306.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met the preamble at trial.
a high frequency power supply;	The Court did not construe this limitation.	Doss '007 discloses using the electrosurgical device with a radio frequency generator. Col. 3, lines 29-38. A radio frequency generator is a high frequency power supply. Dr. Taylor's testimony at Tr. 1306.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
an electrosurgical probe comprising a shaft having a proximal end and a distal end,	"The term 'distal end' shall be construed to mean 'the end situated away from the point of origin or attachment.' The term 'proximal end' shall be construed to mean 'the end situated towards the point of origin or attachment.'" D.I. 353 at 5.	Doss '007 discloses a housing 70 (probe) including concentric electrodes 72 and 74 separated by insulating member 76 (together making up the shaft). The electrodes have a working end (distal end) and a proximal end. Col. 5, lines 27-31. Figure 7 generally shows a distal end and proximal end. Dr. Taylor's testimony at Tr. 1306-07.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.

Anticipation by The Doss '007 Patent
DTX-17

Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an electrode terminal disposed near the distal end, and	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" Id.</p>	<p>Doss '007 discloses an central electrode 72 (electrode terminal, consisting of a single active electrode) at the working (distal) end of the shaft. See, e.g., col. 5, lines 27-41. Figure 7 shows generally the central electrode 72 (electrode terminal) of which only a working end (distal end) is exposed to produce the electric field 102.</p> <p>Dr. Taylor's testimony at Tr. 1307.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.</p>
a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;	<p>"The word connect means 'to bind or fasten together; join or unite; link[.]' The word 'connector,' in terms of the '536 patent, shall be construed to mean 'a structure that electrically links the electrode terminal to the high frequency power supply.'" D.I. 353 at 2.</p>	<p>Doss '007 discloses an operable connection between the tubular electrodes and the RF generator that electrically couples the electrodes to the RF generator. Col. 3, lines 30-34 and Figs. 7 and 9. Further, since the electrodes go through the proximal end, as seen in Fig. 7, Doss '007 discloses a connector under the Courts claim construction.</p> <p>Dr. Taylor's testimony at Tr. 1307</p>	<p>ArthroCare did not introduce any rebuttal evidence.</p> <p>ArthroCare did, however, cross-examine Dr. Taylor with respect to whether the location of the connector is explicitly disclosed in the Doss '007 patent. (Tr. at 1400).</p> <p>However, ArthroCare put forth no evidence which would rebut the disclosure in the Doss '007 patent or Dr. Taylor's testimony.</p>

Anticipation by The Doss '007 Patent
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Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
a return electrode electrically coupled to the electrosurgical power supply; and	"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.	<p>Doss '007 discloses an outer electrode 74 (return electrode), which is electrically coupled to the radio-frequency generator (power supply). See, e.g., col. 5, lines 27-31 and Figs. 7 and 8. As can be seen in Fig. 8, the outer electrode has a larger surface area which affords a lower current density than the smaller inner electrode. Thus, outer electrode 74 satisfies the Court's claim construction for a return electrode.</p> <p>Dr. Taylor's testimony at Tr. 1307 and 1455-57 (emphasis added):</p> <p>Q. Did you use the Court's definition of return electrode in determining whether or not the Doss reference had a return electrode?</p> <p>A. Yes.</p> <p>Q. And what is the critical element of the Court's definition of whether or not something constitutes a return electrode?</p> <p>A. <i>The critical element is an electrode having a larger area of contact than an active electrode, thus affording a lower current density.</i></p> <p>Q. And when you reviewed the Doss patent, did you find such an electrode?</p>	<p>ArthroCare did not introduce any rebuttal evidence.</p> <p>ArthroCare did, however, cross-examine Dr. Taylor with respect to the irrelevant issue of whether the outer electrode in the Doss '007 patent caused a tissue effect.</p> <p>However, in doing so, ArthroCare ignored the Court's claim construction and instead argued its original claim construction, which was rejected by the Court. The Court noted its concern that this might be counter to its claim construction, but let ArthroCare proceed under the impression that ArthroCare was going to show there was <i>no</i> difference (Tr. at 1389):</p> <p>THE COURT: Well, if you are saying there is no difference between the two, I mean I do believe that under this definition there has to be a difference between the active and the return. If you</p>

Anticipation by The Doss '007 Patent
DTX-17

Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
		<p>A. Yes. The outer electrode is -- just look at the geometry --</p> <p align="center">* * *</p> <p>And just on the basis of plane geometry if you assume both electrodes have the same thickness, the outer electrode will have more surface area.</p> <p>Q. And does that outer electrode meet the Court's definition of a return electrode?</p> <p>A. I believe it does.</p>	<p>are saying and your point is that in the [Doss] prior-art reference there is no difference between the two, then that is an appropriate line of cross.</p> <p>However, counsel never attempted to show there was no difference, but rather only that both electrodes had some effect (Tr. at 1396).</p> <p>Thus, ArthroCare did not rebut Smith & Nephew's <i>prima facie</i> showing of invalidity.</p>

Anticipation by The Doss '007 Patent
DTX-17

Claim 45 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
<p>an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.</p>	<p>"Consistent with the prosecution history, the phrase 'electrically conducting fluid supply' shall be construed to mean 'a medical container that stores electrically conducting fluid.' ... An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline." D.I. 353 at 2.</p> <p>"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.</p> <p>Directing or delivering the electrically conductive fluid to the target site "shall be construed consistent with its ordinary meaning; no further construction is necessary." Id. at 3.</p>	<p>Doss '007 discloses a tubular central electrode 72 with an aperture 84 that delivers electrically conducting coolant, such as saline, to the target tissue, which will create a current path between the central electrode 72 and the outer electrode 74. See, col. 3, lines 32-41; col. 6, lines 1-4; col. 3, lines 63 through col. 4, line 7; col. 3, lines 48-54; col. 4, lines 36-40. "A liquid electrically conductive coolant is made to flow through or adjacent to at least one of the electrodes onto the cornea, then, from the cornea, through or adjacent to the other electrode." Col. 2, lines 51-55.</p> <p>Dr. Taylor's testimony at Tr. 1307-08.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.</p>

**Anticipation by The Doss '007 Patent
DTX-17**

Claim 46 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.		Doss '007 discloses all the limitations of claim 45 as shown above.	See above.
	The Court did not construe this limitation.	Doss '007 discloses a central electrode 72 and an outer electrode 74. Col. 5, lines 27-31. These electrodes, together with the insulating member 76, make up the shaft of the electrosurgical probe Fig. 7. Thus, the outer electrode 74 (return electrode) forms a portion of the shaft. Dr. Taylor's testimony at Tr. 1308.	See discussion above regarding ArthroCare's irrelevant cross-examination of Dr. Taylor with respect to whether the return electrode caused a tissue effect.

Claim 47 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
An electrosurgical system as in claim 46 further including an insulating member circumscribing the return electrode,		Doss '007 discloses all the limitations of claim 46 as shown above.	See above.
	"The court shall apply the ordinary definition of the phrase 'insulating member.' Thus, the phrase 'insulating member' shall be construed to mean 'a member which provides a high degree of resistance to the passage of charge.'" D.I. 353 at 4.	Doss '007 discloses a housing 70 which circumscribes the outer (return) electrode 74. Col. 5, lines 27-31. The housing is generally a plastic material (insulating). Col. 4, lines 15-17. Dr. Taylor's testimony at Tr. 1308-09.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode	The Court did not construe this limitation, although it did construe a similar limitation as follows: "The claim limitation 'the return	Doss '007 shows the outer (return) electrode spaced from the inner electrode (electrode terminal). See, e.g., Fig. 7. "The tips of the electrodes are positionable adjacent and spaced from a	See discussion above regarding ArthroCare's irrelevant cross-examination of Dr. Taylor with respect to whether the return electrode

**Anticipation by The Doss '007 Patent
DTX-17**

Claim 47 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
and the patient's tissue.	electrode is not in contact with the body structure' is clear - the return electrode is not to contact the body at all during the performance of the claimed method." <i>Id.</i> at p. 2 (emphasis in original).	subject comes." Col. 2, lines 50-55. Even if the inner electrode were moved into contact with the tissue 78, the spacing of the outer electrode from the electrode terminal (inner electrode) will prevent it from touching the tissue. Dr. Taylor's testimony at Tr. 1309	caused a tissue effect.

Claim 1 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:		Doss '007 describes a bipolar probe, used to apply RF energy to target tissue. See the Abstract; see also col. 1, lines 10-13; col. 2, lines 42-54.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met the preamble at trial.

Anticipation by The Doss '007 Patent
DTX-17

Claim 1 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically conductive fluid;	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" Id.</p> <p>"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.</p>	<p>Doss '007 discloses an inner electrode 72 (electrode terminal) which is an active electrode. Col. 5, lines 27-36. It is positioned over the target tissue in the presence of saline. Col. 3, lines 48-54 and claim 1; <i>see also</i> col. 6, lines 1-4; Fig. 7.</p> <p>Dr. Taylor's testimony at Tr. 1326-27.</p>	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.

**Anticipation by The Doss '007 Patent
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Claim 1 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and	<p>"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.</p> <p>"The claim limitation 'the return electrode is not in contact with the body structure' is clear - the return electrode is not to contact the body at all during the performance of the claimed method." <i>Id.</i> at p. 2 (emphasis in original).</p>	<p>Doss '007 discloses an outer electrode 74 (return electrode) in the saline and not in contact with the target tissue. Col. 5, lines 27-38 and 57-58; Fig. 7.</p> <p>Dr. Taylor's testimony at Tr. 1327</p>	See discussion above regarding ArthroCare's irrelevant cross-examination of Dr. Taylor with respect to whether the return electrode caused a tissue effect.
applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site, and to the return electrode through the current flow path.	<p>"[Through the region of the target site] shall be construed consistent with its ordinary meanings; no further construction is necessary." <i>Id.</i> at 4.</p>	<p>Doss '007 discloses applying RF energy to the electrodes thereby producing a current that flows from the inner electrode, through the target tissue and then to the outer electrode via the saline. Col. 5, lines 38-41; see also current flow lines in Fig. 7.</p> <p>Dr. Taylor's testimony at Tr. 1328</p>	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
Claim 3 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
The method of claim 1 further comprising		Doss '007 discloses all the limitations of claim 1 as shown above.	See above.

Anticipation by The Doss '007 Patent
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Claim 3 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
immersing the target site within a volume of the electrically conductive fluid and	"The court shall apply the ordinary definition of the term 'immersing.' The term 'immersing' shall be construed to mean 'to plunge into or place under a fluid[.]' D.I. 353 at 4.	Doss discloses pumping isotonic saline to the target site. Col. 3, lines 48-54. The saline is contained by skirt 82, which acts as a damming device. Col. 5, lines 31-36; col. 4, lines 19-21. Dr. Taylor's testimony at Tr. 1328-29	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.
positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the electrode terminal and the return electrode.	"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.	Doss discloses that the isotonic saline provides electrical conduction to the target tissue (col. 3, line 65 through col. 4, line 2) and provides a flow path between the inner and outer electrodes (col. 5, lines 31-41; Fig. 7). Dr. Taylor's testimony at Tr. 1328-29	See discussion above regarding ArthroCare's irrelevant cross-examination of Dr. Taylor with respect to whether the return electrode caused a tissue effect.

Claim 4 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
The method of claim 1 further comprising		Doss '007 Patent discloses all the limitations of claim 1 as shown above.	See above.
delivering the electrically conductive fluid to the target site.	"This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary." D.I. 353 at 3.	Doss '007 discloses delivering saline to the target site through the inner electrode. Col. 3, lines 48-54. Dr. Taylor's testimony at Tr. 1329.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.

Anticipation by The Doss '007 Patent
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Claim 11 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
The method of claim 1 wherein		Doss '007 Patent discloses all the limitations of claim 1 as shown above.	See above.
the electrically conductive fluid comprises isotonic saline.	The Court did not construe this limitation.	Doss '007 discloses delivering isotonic saline. Col. 3, lines 65-68. Dr. Taylor's testimony at Tr. 1329.	ArthroCare did not offer any rebuttal evidence or dispute that the Doss '007 patent met this limitation at trial.

Claim 21 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
The method of claim 1 wherein		Doss '007 discloses all the limitations of claim 1 as shown above.	See above.
the voltage is in the range from 500 to 1400 volts peak to peak	"[500 to 1400 Volts Peak to Peak] shall be construed consistent with its ordinary meaning; no further construction is necessary." D.I. 353 at 4.	Doss '007 discloses the use of voltages between about 20 and 200 volts RMS. Col. 3, lines 34-38. The waveform used is not specified but is almost certainly a sine wave. Hence, Doss '007 discloses the use of a voltage range from about 56 to 566 volts peak to peak. Dr. Taylor's testimony at Tr. 1330	ArthroCare did not introduce any rebuttal evidence. ArthroCare did, however, cross-examine Dr. Taylor with respect to whether Doss explicitly disclosed a sine wave. (Tr. at 1402). However, ArthroCare did not rebut Smith & Nephew's <i>prima facie</i> showing, nor did it overcome Dr. Taylor's testimony that, even if not explicitly disclosed, the waveform was inherently disclosed (Tr. at 1402):

**Anticipation by The Doss '007 Patent
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Claim 21 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence re: the Doss '007 Patent	ArthroCare's Position
			A. ...[T]o my knowledge, there are no commercially-available square wave generators.

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Antikickback by The Slager Article
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Claim 1 of the '882' Patent A method for applying energy to a target site on a patient body structure comprising:	The Court's Claim Construction	Smith & Nephew's Evidence	ArturoCare's Position
		<p>The Slager Article generally discloses applying HF energy to a target site (the heart). Specifically, the Slager Article discloses in-vitro tests on aortic tissue in a lab dish. p. 1383.</p> <p>Dr. Taylor's testimony at Tr. 1318.</p>	<p>ArturoCare did not introduce any rebuttal evidence.</p> <p>ArturoCare did, however, cross-examine Dr. Taylor with respect to whether the Slager Article disclosed applying energy to a patient body structure because it describes in-vitro tests.</p> <p>However, ArturoCare's apparent position was undercut by Phillip Eggers, one of the inventors of the patents-in-suit, who testified that the inventions were reduced to practice by similar in-vitro experiments on chicken parts in bowls of saline (Tr. at 295).</p> <p>Thus, ArturoCare did not rebut Smith & Nephew's <i>prima facie</i> showing of invalidity.</p>

¹ For this analysis only, Smith & Nephew will assume the Certificate of Correction is valid.

Anticipation by The Slager Article
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Claim 1 of the '882 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
providing an electrode terminal and	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" Id.</p>	<p>The spark electrode in Slager is an electrode terminal consisting of an active electrode. p. 1383.</p> <p>Dr. Taylor's testimony at Tr. 1318.</p>	ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.
a return electrode electrically coupled to a high frequency voltage source;	<p>"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.</p> <p>"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.</p>	<p>Slager discloses a return electrode electrically coupled to an HF voltage source. p. 1383.</p> <p>Dr. Taylor's testimony at Tr. 1318.</p>	ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.
positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and		<p>The spark (active) electrode in Slager is contacted to the target site (arterial plaque) in the presence of saline, which is an electrically conductive fluid. p. 1383.</p> <p>Dr. Taylor's testimony at Tr. 1318-19.</p>	ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.

Anticipation by The Slager Article
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Claim 1 of the '882' Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.	The Court did not construe this limitation.	A HF voltage is applied between the spark electrode (electrode terminal) and return electrode, resulting in the formation of bubbles and a steam layer over the spark electrode, discharging energy to the target site in contact with the vapor layer. pp. 1383-84, Fig. 4. Dr. Taylor's testimony at Tr. 1319.	ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.

Claim 13 of the '882	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.	The Court did not construe this limitation.	The Slager Article discloses all the limitations of Claim 1 as show above. The Slager Article specifically mentions sparking during operation. pp. 1382-85. This inherently results in the emission of UV and other wavelengths of light. Dr. Taylor's testimony at Tr. 1319; see also Tr. 1419-20 (emphasis added): Q. So just from seeing a spark, just from seeing that flash of light with the naked eye, you can't tell whether or not there is ultraviolet light in there or whether there isn't. True? A. <i>That's true, except you can't have a spark in aqueous solution without the UV light.</i> * * *	See above. ArthroCare did not introduce any rebuttal evidence. ArthroCare did, however, cross-examine Dr. Taylor with respect to whether the Slager Article explicitly disclosed the production of UV photons. However, ArthroCare produced no evidence to rebut Dr. Taylor's testimony that the production of UV photons is inherent in the methods disclosed in the Slager Article. Thus, ArthroCare did not rebut Smith & Nephew's

Anticipation by The Slager Article
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Claim 13 of the '882	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
		<p>Q. So you didn't do any tests and you didn't look at the literature; correct?</p> <p>A. <i>Right. One has to realize, though, that if you have a spark in an aqueous solution, especially a sodium chloride aqueous solution, that you will generate UV photons because of the transition of the hydroxyl ion. You will also generate what we would consider to be orange, yellowish-orange light, 580 nanometers, because of the sodium ion transition. That is college chemistry.</i></p>	<i>prima facie</i> showing of invalidity.

Claim 17 of the '882	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.	The Court did not construe this limitation.	<p>The Slager Article discloses all the limitations of Claim 1 as shown above.</p> <p>The Slager Article uses a HF voltage of 1200 volts peak to peak. p. 1383.</p> <p>Dr. Taylor's testimony at Tr. 1320.</p>	See above.
			ArthroCare did not offer any actual evidence or dispute that the Slager Article met this limitation at trial.

Claim 54 of the '882	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
The method of claims 23 or 48 further comprising		The Slager Article discloses all the limitations of claims 1 and 28 as show above.	See above.

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Claim 54 of the '882 evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.	The Court's Claim Construction The Court did not construe this limitation.	Smith & Nephew's Evidence The Slager Article teaches that a suction technique may be used to remove bubbles generated at the target site. p. 1386. Dr. Taylor's testimony at Tr. 1320.	ArthroCare's Position ArthroCare did not introduce any rebuttal evidence. ArthroCare did cross-examine Dr. Taylor with respect to whether the Slager Article explicitly discloses a specific suction technique. However, ArthroCare provided no evidence to rebut Dr. Taylor's testimony that the evacuation by a suction lumen adjacent the electrode terminal is inherently disclosed. Thus, ArthroCare failed to rebut Smith & Nephew's <i>prima facie</i> showing of invalidity.
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Claim 23 of the '592 A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:	The Court's Claim Construction	Smith & Nephew's Evidence The Slager Article generally describes application of high frequency current to vaporize tissue (target site).	ArthroCare's Position See discussion above regarding ArthroCare's cross-examination of Dr. Taylor with respect to in-vitro tests.
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Anticipation by The Slager Article
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Claim 23 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
contacting an active electrode with the body structure in the presence of an electrically conductive fluid;	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" Id.</p> <p>"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.</p>	<p>The spark (active) electrode in Slager is contacted to the target site (arterial plaque) in the presence of saline, which is an electrically conductive fluid. p. 1383.</p> <p>Dr. Taylor's testimony at Tr. 1331.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.</p>

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Claim 23 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and	"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4. "The claim limitation 'the return electrode is not in contact with the body structure' is clear - the return electrode is not to contact the body at all during the performance of the claimed method." <i>Id.</i> at p. 2 (emphasis in original).	The return electrode in Slager is positioned within saline, which is an electrically conductive fluid. p. 1383-84. The aortic segment is disclosed as being approximately 4 x 7 cm in size. P. 1382. The distance between the active and return "electrodes is varied from 2 to 10 cm." P. 1383. Thus, at least when the active and return electrodes are 7 to 10 cm apart, the return electrode cannot be touching the aortic segment (body structure). Thus, the Slager Article explicitly discloses this limitation. Dr. Taylor's testimony at Tr. 1331	ArthroCare did not introduce any rebuttal evidence. Instead, ArthroCare asked misleading and irrelevant questions regarding the <i>in-vivo</i> test, which is a different test in the article on which it knew Dr. Taylor did not rely. (Tr. at 1414-18). Thus, ArthroCare did not rebut Smith & Nephew's <i>prima facie</i> showing of invalidity.
applying a high frequency voltage difference between the active electrode and the return electrode such that an electrical current flows from the active electrode, through the electrically conductive fluid, and to the return electrode.	The Court did not construe this limitation.	A HF voltage is applied between the spark electrode (electrode terminal) and return electrode, resulting in the flow of an electric current between them and through the electrically conductive fluid. pp. 1383-84. Dr. Taylor's testimony at Tr. 1332.	ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.

Claim 26 of the '592	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
The method of claim 23 further comprising		The Slager Article discloses all the limitations of claim 23 as show above.	See above.

Anticipation by The Slager Article
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Claim 26 of the '592 immersing the target site within a volume of the electrically conductive fluid and	The Court's Claim Construction "The court shall apply the ordinary definition of the term 'immersing.' The term 'immersing' shall be construed to mean 'to plunge into or place under a fluid[.]' D.I. 353 at 4. "As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.	Smith & Nephew's Evidence The target site is immersed in saline, which is an electrically conductive fluid. p. 1383 Dr. Taylor's testimony at Tr. 1332 The return electrode in Slager is positioned within saline, which is an electrically conductive fluid. p. 1383-84. The aortic segment is disclosed as being approximately 4 x 7 cm in size. P. 1382. The distance between the active and return "electrodes is varied from 2 to 10 cm." P. 1383. Thus, at least when the active and return electrodes are 7 to 10 cm apart, the return electrode cannot be touching the aortic segment (body structure). Thus, the Slager Article explicitly discloses this limitation.	ArthroCare's Position ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial. ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.
Claim 27 of the '592. The method of claim 23 further comprising delivering the electrically conductive fluid to the target site.	The Court's Claim Construction "This phrase shall be construed consistent with its ordinary meaning; no further construction is necessary." D.I. 353 at 3.	Smith & Nephew's Evidence The Slager Article discloses all the limitations of claim 23 as show above. The Slager Article discloses immersing the target site in saline. p. 1383. Dr. Taylor's testimony at Tr. 1333.	ArthroCare's Position See above. ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.
Claim 32 of the '592 The method of claim 23 wherein	The Court's Claim Construction	Smith & Nephew's Evidence The Slager Article discloses all the limitations of claim 1 as show above.	ArthroCare's Position See above.

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Claim 32 of the '592 the electrically conductive fluid comprises isotonic saline.	The Court's Claim Construction The Court did not construe this limitation.	Smith & Nephew's Evidence The Slager Article specifically mentions using 0.9% (isotonic) saline (p. 1383) as the conducting fluid. Dr. Taylor's testimony at Tr. 1333.	ArthroCare's Position ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.
Claim 42 of the '592 The method of claim 23 wherein the voltage is in the range from 500 to 1400 volts peak to peak.	The Court's Claim Construction "[500 to 1400 Volts Peak to Peak] shall be construed consistent with its ordinary meaning; no further construction is necessary." D.I. 353 at 4.	Smith & Nephew's Evidence The Slager Article discloses all the limitations of claim 23 as show above. Slager specifically discloses the use of a voltage of 1200 volts peak to peak (1383). Dr. Taylor's testimony at Tr. 1333.	ArthroCare's Position See above. ArthroCare did not offer any rebuttal evidence or dispute that the Slager Article met this limitation at trial.

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Anticipation by The Roos '198 Patent
DTX-11

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electro-surgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	"The court shall apply the ordinary definition of the term 'system.' The term 'system' shall be construed to mean 'an assemblage or combination of things or parts forming a unitary whole.'" D.I. 353 at 5.	The abstract of Roos '198 generally describes that the Roos invention is an electro-surgical device used to separate or coagulate tissue in a patient. See also, col. 1, lines 1-22. All of the components, including the fluid supply, are combined as a unitary whole in the device. Dr. Taylor's testimony at Tr. 1301.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met the preamble at trial.
a high frequency power supply;	The Court did not construe this limitation.	Roos '198 discloses a high frequency generator throughout. See, e.g., Claim 1 at col. 7, lines 51-53; col. 7, lines 5-7; and col. 1, lines 5-17. Dr. Taylor's testimony at Tr. at 1302.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.
an electro-surgical probe comprising a shaft having a proximal end and a distal end,	"The term 'distal end' shall be construed to mean 'the end situated away from the point of origin or attachment.' The term 'proximal end' shall be construed to mean 'the end situated towards the point of origin or attachment.'" D.I. 353 at 5.	Roos '198 discloses a shaft (endoscope) having a front end (distal end) and a rear portion (proximal end). See col. 6, lines 61-68. See also Fig. 7 and 8, which generally shows a distal end. Dr. Taylor's testimony at Tr. at 1302.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.

Anticipation by The Roos '198 Patent
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Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an electrode terminal disposed near the distal end, and	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" Id.</p>	<p>Roos '198 discloses a treatment electrode, consisting of a single active electrode, projecting from the front (distal) end of the endoscope (shaft). See, e.g., col. 6, lines 67-68; Claim 1 at col. 7, lines 47-48. See also Fig. 7, which generally shows a treatment electrode (12) at the distal end of the endoscope (13).</p> <p>Dr. Taylor's testimony at Tr. at 1302.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.</p>
a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electro-surgical power supply;	<p>"The word connect means 'to bind or fasten together; join or unite; link[.]' The word 'connector,' in terms of the '536 patent, shall be construed to mean 'a structure that electrically links the electrode terminal to the high frequency power supply.'" D.I. 353 at 2.</p>	<p>Roos '198 discloses a connector near the proximal end of the endoscope (shaft). "In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of the endoscope 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator..." Col. 7, lines 1-7 (emphasis added). Figure 7 and claim 1 further disclose a connector – "insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator..." Claim 1 at col.</p>	<p>ArthroCare did not introduce any rebuttal evidence. This was not surprising, since in the pretrial proceedings, ArthroCare's expert, Dr. Goldberg, had already admitted that the Roos '198 patent discloses a connector near the proximal end of the shaft. (Goldberg Dep. at 521-22, Exhibit ____).</p> <p>ArthroCare did, however, attempt to cross-examine Dr. Taylor with respect to</p>

Anticipation by The Roos '198 Patent
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Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
		<p>7, lines 50-53; <i>see also</i> Claim 15, col. 8, lines 49-52 (which discloses a connector separate from the cable means). Also Figs. 4-6 show the connector schematically.</p> <p>Dr. Taylor's testimony at Tr. at 1302-03.</p>	<p>whether the location of the connector is explicitly disclosed in the Roos '198 patent (Tr. at 1371-72):</p> <p>A. Well, there is a connector. There has to be.</p> <p>Q. I am not asking you that question. I am saying that you have been able to review the '198 patent and you have been able to discern some description in there of the location of the connector. Not that there is one. But the specific location of it; right?</p> <p>A. There is not a specific reference to a location of the connector.</p> <p>However, ArthroCare did not rebut Smith & Nephew's <i>prima facie</i> showing, as Dr. Taylor explained the location of the connector was inherently disclosed (Tr. at 1370-72):</p> <p>A. You do realize that all resectoscopes have</p>

Anticipation by The Roos '198 Patent
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Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
a return electrode electrically coupled to the electrosurgical power supply; and	"As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.	Roos '198 discloses a return electrode electrically coupled to the high frequency generator (power supply). See, e.g., Claim 1 at col., 7, lines 52-53; col. 7, lines 5-7. See also Figs. 4-6, 8 and 9.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.
an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.	"Consistent with the prosecution history, the phrase 'electrically conducting fluid supply' shall be construed to mean 'a medical container that stores electrically conducting fluid.' ... An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline." D.I. 353 at 2.	Dr. Taylor's testimony at Tr. at 1303. Roos '198 explicitly discloses an electrically conducting fluid supply for generating a current flow path between the return electrode and electrode terminal. Claim 1 requires: [A] space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes. Claim 1 at col. 7 (emphasis added), lines 59-62; see also col. 4, lines 53-55 and Fig. 1: col. 1, lines	ArthroCare did not offer any rebuttal evidence. ArthroCare did cross-examine Dr. Taylor with respect to whether the Roos '198 patent explicitly discloses electrically conductive fluid. However, ArthroCare did not provide any evidence to rebut Smith

Anticipation by The Roos '198 Patent
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Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
	<p>"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.</p> <p>Directing or delivering the electrically conductive fluid to the target site "shall be construed consistent with its ordinary meaning; no further construction is necessary." Id. at 3.</p>	<p>52-56. Liquid to <i>provide</i> electrical conductance clearly fits the Court's claim construction of "fluid that facilitates the passage of electrical current."</p> <p>Dr. Taylor's testimony at Tr. at 1303-04 (emphasis added):</p> <p>Q. Have you done an element-by-element comparison of the teachings of the Roos '198 with the claims of the '536 patent?</p> <p>A. Yes, I have.</p> <p>Q. Have you prepared some slides to illustrate that?</p> <p>A. Yes, I have. ...</p> <p><i>It also requires an electrically conducting fluid supply, directed to the target site and generating current, flow path between the active and return electrode. That is diagrammatically shown here in Figures 7 and 8 and also specifically called out in Claim 1, basically the last line in Claim 1. So that element is satisfied.</i></p> <p>Q. Just to pause on this one for a moment, that language that is quoted</p>	<p>& Nephew's <i>prima facie</i> showing of invalidity.</p>

Anticipation by The Roos '198 Patent
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Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
		below the drawing comes from Claim 1 of the Roos '198 patent? A. That's correct. Q. That is where you found support for the electrically conducting fluid limitation? A. Yes.	

Claim 46 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electrosurgical system as in claim 45, wherein the return electrode forms a portion of the shaft of the electrosurgical probe.	The Court did not construe this limitation.	Roos '198 discloses all the limitations of claim 45 as show above. In the device of Figures 7 and 8 of Roos '198, neutral electrode 11 (the "return electrode") forms a portion of the endoscope, which is the shaft of the probe. Dr. Taylor's testimony at Tr. at 1304.	See above. ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.

Claim 47 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
An electrosurgical system as in claim 46 further including		Roos '198 discloses all the limitations of claim 46 as show above.	See above.

Anticipation by The Roos '198 Patent
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Claim 47 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an insulating member circumscribing the return electrode,	"The court shall apply the ordinary definition of the phrase 'insulating member.' Thus, the phrase 'insulating member' shall be construed to mean 'a member which provides a high degree of resistance to the passage of charge.'" D.I. 353 at 4.	Figures 7 and 8 show an insulating member 35 which circumscribes the return electrode at the front of the resectoscope. Col. 7, lines 8-16. Dr. Taylor's testimony at Tr. at 1304.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.
the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.	The Court did not construe this limitation, although it did construe a similar limitation as follows: "The claim limitation 'the return electrode is not in contact with the body structure' is clear - the return electrode is not to contact the body at all during the performance of the claimed method." / <i>Id.</i> at p. 2 (emphasis in original).	The return electrode disclosed is spaced away from the electrode terminal and separated by the insulating member 35. See, e.g., Figs. 7 and 8. Thus, the return is sufficiently spaced to minimize contact between the return electrode and the patient's tissue. Dr. Taylor's testimony at Tr. at 1304-05.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.

Claim 56 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence re: the Roos '198 Patent	ArthroCare's Position
The electrosurgical system of claim 45 wherein		Roos '198 discloses all the limitations of claim 45 as show above.	See above.

Anticipation by The Roos '198 Patent
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Claim 56 of the '536	The Court's Claim Construction	Smith & Nephew's Evidence re: the Roos '198 Patent	ArthroCare's Position
the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.	The Court did not construe this limitation.	The target sites of the electrosurgical system described in Roos '198 are the prostate or bladder, which are in the abdominal cavity. See Col. 1, lines 18-22. Dr. Taylor's testimony at Tr. at 1305.	ArthroCare did not offer any rebuttal evidence or dispute that the Roos '198 patent met this limitation at trial.

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Anticipation by The Elsäßer/Roots Article
DTX-59A and 59B

<u>Claim 45 of the '536 Patent</u> An electrosurgical system for applying electrical energy to a target site on a structure within or on a patient's body, the system comprising:	<u>The Court's Claim Construction</u> "The court shall apply the ordinary definition of the term 'system.' The term 'system' shall be construed to mean 'an assemblage or combination of things or parts forming a unitary whole.'" D.I. 353 at 5.	<u>Smith & Nephew's Evidence</u> The Elsäßer and Roots Article generally describes an electrosurgical device (i.e. resectoscope) which applies high frequency current to tissue (a target site) for electroresections. See p. 5 of translation. All of the components, including the fluid supply, are combined as a unitary whole in the device.	<u>ArthroCare's Position</u> ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met the preamble at trial.
a high frequency power supply;	The Court did not construe this limitation.	Dr. Taylor's testimony at Tr. 1295-96. The Elsäßer and Roots Article discloses a high frequency power supply. See p. 5 of translation.	ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met this limitation at trial.
an electrosurgical probe comprising a shaft having a proximal end and a distal end,	"The term 'distal end' shall be construed to mean 'the end situated away from the point of origin or attachment.' The term 'proximal end' shall be construed to mean 'the end situated towards the point of origin or attachment.'" D.I. 353 at 5.	Dr. Taylor's testimony at Tr. 1296. The Elsäßer and Roots Article discloses a resectoscope (probe) shaft having a proximal end and a distal end. See p. 5 of translation and Figs. 8 and 9. Dr. Taylor's testimony at Tr. 1297-98.	ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met this limitation at trial.

Anticipation by The Elsäßer/Roots Article
DTX-59A and 59B

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an electrode terminal disposed near the distal end, and	<p>"Consistent with the intrinsic evidence of the patents in suit, 'electrode terminal' means 'one or more active electrodes.'" D.I. 353 at 3.</p> <p>"The court shall apply the ordinary definition of the term 'active electrode' in the relevant art. The term 'active electrode' means 'a stimulating electrode ... applied to tissue for stimulation and distinguished from [a return electrode] by having a smaller area of contact, thus affording a higher current density.'" Id.</p>	<p>The Elsäßer and Roots Article discloses an electrode terminal consisting of a single active electrode -- a cutting loop -- located at the distal end of the resectoscope (shaft). See p. 5 of translation and Figs. 8 and 9.</p> <p>Dr. Taylor's testimony at Tr. 1298.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met this limitation at trial.</p>
a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply;	<p>"The word connect means 'to bind or fasten together; join or unite; link[.]' The word 'connector,' in terms of the '536 patent, shall be construed to mean 'a structure that electrically links the electrode terminal to the high frequency power supply.'" D.I. 353 at 2.</p>	<p>The Elsäßer and Roots Article clearly discloses a connector near the proximal end of the resectoscope (shaft) electrically linking the cutting loop (electrode terminal) to the high frequency power supply. See p. 5 of translation and Figs. 8 and 9.</p> <p>Dr. Taylor's testimony at Tr. 1298.</p>	<p>ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met this limitation at trial.</p>

Anticipation by The Elsäßer/Roots Article
DTX-59A and 59B

Claim 45 of the '536 Patent a return electrode electrically coupled to the electrosurgical power supply; and	The Court's Claim Construction "As contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" D.I. 353 at 4.	Smith & Nephew's Evidence Elsässer and Roots Article discloses a neutral electrode (return electrode) connected to the high frequency power supply. See p. 5 of translation and Figs. 8 and 9. The neutral electrode has a larger area of contact than the cutting loop (active electrode).	ArthroCare's Position ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met this limitation at trial.
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Dr. Taylor's testimony at Tr. 1298-99.

Anticipation by The Elsässer/Roots Article
DTX-59A and 59B

Claim 45 of the '536 Patent	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
an electrically conducting fluid supply for directing electrically conducting fluid to the target site such that the electrically conducting fluid generates a current flow path between the return electrode and the electrode terminal.	<p>"Consistent with the prosecution history, the phrase 'electrically conducting fluid supply' shall be construed to mean 'a medical container that stores electrically conducting fluid.' ... An example of a medical container is an IV bag. An example of electrically conducting fluid is isotonic saline." D.I. 353 at 2.</p> <p>"Consistent with the ordinary definition, 'electrically conducting fluid' and 'electrically conductive fluid' shall be construed to mean 'any fluid that facilitates the passage of electrical current.' Examples of electrically conducting fluids are blood and saline." Id. at 3.</p> <p>Directing or delivering the electrically conductive fluid to the target site "shall be construed consistent with its ordinary meaning; no further construction is necessary." Id. at 3.</p>	<p>"[The device] offer[s] the high-frequency current a path to balance the potential difference that would be so short and offer such a low resistance that aberrant currents or leakage currents do not even occur... The current flows directly from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid." P. 4 of translation (emphasis added); see also p. 5 and Figs. 8 & 9.</p> <p>Dr. Taylor's testimony at Tr. 1299.</p>	<p>ArthroCare did not offer any rebuttal evidence.</p> <p>ArthroCare did cross-examine Dr. Taylor with respect to whether the Elsässer and Roots Article disclosed electrically conductive fluid. However, ArthroCare did not rebut Dr. Taylor's testimony on this point, nor did it overcome the explicit disclosure found in the Elsässer and Roots Article</p>

**Anticipation by The Elsäßer/Roots Article
DTX-59A and 59B**

Claim 46 of the '536 Patent An electro-surgical system as in claim 45, wherein	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
the return electrode forms a portion of the shaft of the electro-surgical probe.	The Court did not construe this limitation.	The Elsäßer and Roots Article discloses all the limitations of claim 45 as shown above. In the device of Figs. 8 and 9 of the Elsäßer and Roots Article, the "metal ring" that forms the neutral (return) electrode also forms a portion of the endoscope, which is the shaft of the probe -- "the incorporation of the neutral electrode as a metal ring into the end of the resectoscope shaft... [has] proved successful." P. 5 of the translation. Dr. Taylor's testimony at Tr. 1299-300.	See above. ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met this limitation at trial.

Claim 56 of the '536 Patent The electro-surgical system of claim 45 wherein	The Court's Claim Construction	Smith & Nephew's Evidence	ArthroCare's Position
the target site is selected from the group consisting essentially of the abdominal cavity, thoracic cavity, knee, shoulder, hip, hand, foot, elbow, mouth, spine, ear, nose, throat, epidermis and dermis of the patient's body.	The Court did not construe this limitation.	The Elsäßer and Roots Article discloses all the limitations of claim 45 as shown above. The target sites described in the Elsäßer and Roots Article are the prostate and bladder, which are located in the abdominal cavity. P. 5 of translation. Dr. Taylor's testimony at Tr. 1300.	See above. ArthroCare did not offer any rebuttal evidence or dispute that the Elsäßer/Roots Article met this limitation at trial.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.,

Defendant.

C.A. No. 01-504 (SLR)

**ARTHROCARE'S ANSWERING BRIEF IN OPPOSITION
TO SMITH & NEPHEW'S RULE 50(b) MOTION FOR
JUDGMENT AS A MATTER OF LAW**

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July 30, 2003

A 17901

patent had substantially the same current density." (Tr. 1385). Thus, the Doss '007 patent does not disclose a return electrode because the Court's claim construction requires a return electrode to have a "lower current density" than the active electrode.

2. The Jury's Verdict That Neither The Roos And Elsässer Article Nor The Roos '198 Patent (the "Roos References") Anticipates The '536 Patent Should Not Be Disturbed.

The jury's determination that Smith & Nephew failed to meet its burden of proving invalidity is substantially supported by the fact that the Roos references were disclosed to the PTO during the reexamination of the '536 patent. (Tr. 1336-38, PX 7). A board of three examiners reviewed the patentability of the asserted claims of the '536 patent in light of the Roos references during the reexamination and concluded that they did not render any of the claims unpatentable. (Tr. 1337-38). The PTO issued a Notice of Intent to Issue Reexamination Certificate on March 14, 2003. (Tr. 1538-40). Thus, the jury's determination that Smith & Nephew failed to meet its burden as to the Roos references must be viewed in light of the fact that Smith & Nephew's burden in proving anticipation was "more difficult" to meet.

As with the Doss '007 patent, Smith & Nephew failed to show that there is a connector near the proximal end of the shafts of the devices disclosed in the Roos references that connects the electrode terminal to the generator, as required by claims 46, 47 and 56 of the '536 patent. Dr. Taylor admitted that there is no disclosure of the location of a connector anywhere in the Roos '198 patent. (Tr. 1371-72). As for the Roos and Elsässer article, Dr. Taylor identified no disclosure in the article which described the function of the structure at the proximal end of the device which he contended was a connector. (Tr. 1298). The jury was free to disregard his testimony as insufficient to show a connector for "electrically coupling the electrode terminal to

¹¹ Although Dr. Taylor tried to explain away his deposition testimony as a mistake, the jury was free to reject his trial testimony. (Tr. 1385-86).

the electrosurgical power supply," especially since Dr. Taylor had used the word "connector" to describe a structure that connected the device in the Pao '499 patent to a fluid supply. (Tr. 1311). In light of this lack of evidence of a connector, Smith & Nephew cites to several passages in the Roos references in a misguided attempt to show that a connector is inherent. The first passage Smith & Nephew quotes (D.I. 459 at 30) is from the '198 patent and discusses a cable leading to the return electrode, not a connector for electrically coupling the active electrode, as required by the asserted claims. The second passage Smith & Nephew cites, also from the '198 patent, discusses only an "insulated cable means," which is a conductor, not a connector, and in any event does not disclose its location with respect to the proximal end. (*Id.*) Finally, Smith & Nephew points to figure 9 in the Roos and Elsässer article as evidence of a connector. (D.I. 459 at 30). Figure 9, however, does not disclose what the structure at the proximal end actually does, such as whether it connects the active electrode, the return electrode, or a fluid supply, or has some other function altogether.

Dr. Taylor's testimony also did not establish that a connector near the proximal end of the shaft for coupling the electrode terminal to the generator is inherently disclosed in either of the Roos references. As Smith & Nephew points out, Dr. Taylor testified that "you do realize that all resectoscopes have connectors at the back of the resectoscope." (Tr. 1371). This testimony, however, was properly rejected by the jury because it lacked any basis, was conclusory, was not corroborated with any documents, and does not specify what the "connector" couples together. Similarly, Dr. Taylor's testimony that "there are no resectoscopes on the market that don't have a connector at the end, on the back of the resectoscope" (Tr. 1372) is insufficient because the mere fact that devices on the market today may have connectors does not establish (a) that the connector is one that connects the electrode terminal to the generator, or (b) that a connector is inherent in the Roos references that were published over 20 years ago. *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2002) ("inherent anticipation requires that the missing

descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art").

Dr. Taylor's admissions also clearly establish that the Roos references do not disclose the use of an electrically conducting fluid. Dr. Taylor testified that the Roos references do not disclose the use of either saline or Ringer's lactate. (Tr. 1340-43, 1375). He also testified that the Roos references describe the use of prior art monopolar devices for TURP procedures, in addition to the bipolar devices Smith & Nephew alleges anticipate. (Tr. 1340-42, 1374-75). As Dr. Taylor testified, the liquid used in these prior art monopolar devices for TURP procedures was electrically non-conducting. (*Id.*). This is significant because Dr. Taylor conceded that the Roos references do not differentiate between the liquid used with the bipolar devices and the liquid used with the monopolar devices. (Tr. 1343-44 ("washing water" and "washing liquid"), 1376-77 ("irrigation liquid"), 1350-51). From this, the jury was free to conclude that the liquid described in the Roos references was not electrically conducting fluid.

In addition, Dr. Taylor's testimony as to Figure 5 of the Roos '198 patent establishes that the fluid it mentioned was not electrically conducting. Dr. Taylor agreed that if the liquid disclosed in Figure 5 of the Roos '198 patent were electrically conducting, there would be no need for the steel band described in Figure 5 to rest "on the tissue in large area form so that good electrical contact is ensured," as described in the '198 patent (Tr. 1345). Because Dr. Taylor testified that the same fluid is used for all of the embodiments of the '198 patent, there can be no doubt that the fluid disclosed in the '198 patent was not electrically conducting. (Tr. 1343-44, 1350-51, 1376-77).

Dr. Taylor's testimony concerning a later issued patent to Roos, the '667 patent, also shows that the fluid mentioned in the '198 patent was not electrically conducting. Specifically, Dr. Taylor agreed that if the fluid used in '198 patent had been an electrically conducting fluid, then the subsequent '667 patent would not have stated, as it did, that the device in the '198 patent did not work. (Tr. 1364-66). Moreover, Dr. Taylor conceded that if the device disclosed in the

'198 patent had used electrically conducting fluid, then the '667 patent would not have described the return electrode of the '198 patent as only being able to "enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process." (Tr. 1366). In light of Dr. Taylor's admissions, the jury was free to conclude that Smith & Nephew did not meet its burden of proving that the Roos '198 patent anticipated the asserted claims of the '536 patent.

Smith & Nephew makes much of the fact that claim 1 of the '198 patent refers to "liquid to provide electrical conductance."¹² (D.I. 459 at 32). This statement, however, begs the question rather than answering it. Dr. Taylor readily conceded that even non-conducting fluids will conduct electrical current. (Tr. 1373-75). This testimony is consistent with Figure 3 of the Roos and Elsässer article, which clearly shows current flux lines passing from the treatment electrode to the endoscope shaft through electrically non-conducting fluid. (*Id.*, DTX 594A). From this, the jury was free to conclude that simply because a fluid will conduct some amount of current does not make it an electrically conducting fluid, and thus that Smith & Nephew failed to show anticipation by clear and convincing evidence with the Roos references.

¹² Smith & Nephew also cites to the Roos and Elsässer article, which states that "[the device] offer[s] the high-frequency current a path to balance the potential difference that would be so short and offer such a low resistance that aberrant currents or leakage do not even occur." (D.I. 459 at 32). Smith & Nephew did not argue at trial that this portion of the Roos article discloses an electrically conducting fluid, nor could it have, because this portion of the article is not referring to the conductive qualities of the fluid. Instead, it is referring to the relatively lower resistance between the electrodes in the bipolar, as opposed to monopolar, configurations that results from the shorter distance between electrodes in a bipolar device (both electrodes are positioned close together in the vicinity of the surgical site) than in a monopolar device (the return electrode is positioned away from the surgical site outside the patient's body).

FILED
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE
2004 MAR 12 PM 4:37

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

SMITH & NEPHEW, INC.'S
MOTION TO STAY INJUNCTION

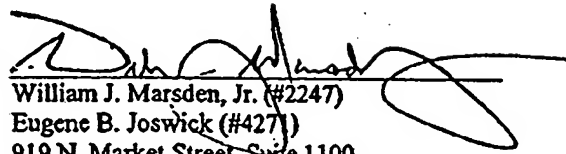
Defendant Smith & Nephew, Inc. ("Smith & Nephew") hereby moves this Court for an order staying the injunction granted by the Court's March 10, 2004 Order pending the outcome of appeal for the reasons more fully set forth in the memorandum accompanying this motion

A 18165

Dated: March 12, 2004

FISH & RICHARDSON P.C.

By:



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A 18166

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

PROPOSED ORDER

The Court having considered the motion to stay injunction, filed by Smith & Nephew, and all supporting memoranda and exhibits, and ArthroCare's response thereto, and good cause having been shown therefore:

IT IS HEREBY ORDERED this _____ day of _____, 2004 that the injunction granted by the Court's March 10, 2004 Order (D.I. 483) be stayed pending the outcome of the appeal.

UNITED STATES DISTRICT JUDGE

A 18167

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of March, 2004, a true and correct copy of
SMITH & NEPHEW, INC.'S MOTION TO STAY INJUNCTION was caused to be
served on the attorneys of record at the following addresses as indicated:

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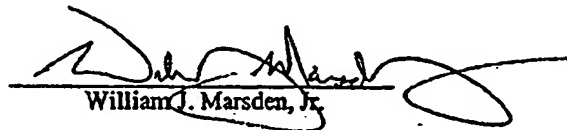
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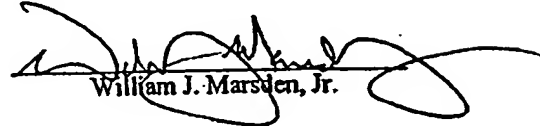

William J. Marsden, Jr.

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RULE 7.1.1 CERTIFICATE

I hereby certify that I have made a reasonable effort to contact counsel for ArthroCare on the matters set forth in the Motion. I further certify that I have been unable to reach ArthroCare's counsel and reasonably assume that ArthroCare opposes the Motion.

Dated: March 12, 2003


William J. Marsden, Jr.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,
Plaintiff,

v.

SMITH & NEPHEW, INC.
Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,
Counterclaim Plaintiff,
v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,
Counterclaim Defendants.

CONFIDENTIAL
FILED UNDER SEAL

SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS
MOTION TO STAY INJUNCTION

Dated: March 12, 2004

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A 18170

**These pages have been removed from the
non-confidential appendix due to confidential
designations**

A 18178 - 18182

**These pages have been removed from the
non-confidential appendix due to confidential
designations**

A 18189 - 18193



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(THIRD PARTY REQUESTERS CORRESPONDENCE ADDRESSED TO)

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7 RECEIVED

JUL 03 2003

FISH & RICHARDSON, P.C.
BOSTON OFFICE

REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/006,597

PATENT NO. 5,677,536

ART UNIT 3763

Enclosed is a copy of the latest communication from the Patent and Trademark Office in the above identified reexamination proceeding. 37 C.F.R. 1.550(e).

Where this copy is supplied after the reply by requester, 37 C.F.R. 1.535, or the time for filing a reply has passed, no submissions on behalf of the reexamination requester will be acknowledged or considered. 37 C.F.R. 1.550(e).

Docketed By	Practice Exam.
Action	Patent Office
See Also	10/10/03
Due Date	8/15/03
Deadline	8/15/03
Initials	WJ
Record	

Docketed By	Billing
Due Date	8/15/03
Deadline	
Initials	WJ

PTOL-448 (2-00)

A 18215



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,597	APRIL 9, 2003	5,697,536	

JOHN T. RAFFLE
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680 VAQUEROS AVENUE
SUNNYVALE, CA 94085

EXAMINER

HAYES, M.

ART UNIT

PAPER

3763

6

DATE MAILED: JUNE 30, 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

cc: William E. Booth, 3rd party
attorney

PTO-50C (Rev. 3-88)

A 18216

Order Granting / Denying Request For Ex Parte Reexamination	Control No. 90/006,897	Patent Under Reexamination 6697636	
	Examiner Michael J Hayes	Art Unit 3763	

-The MAILING DATE of this communication appears on the cover sheet with the correspondence address-

The request for ex parte reexamination filed 09 April 2003 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) ☐ PTO-892, b) ☒ PTO-1449, c) ☐ Other: _____

1. ☒ The request for ex parte reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(e).

For Requester's Reply (optional): TWO MONTHS from the date of service of any timely filed Patent Owner's Statement (37 CFR 1.535). NO EXTENSION OF THIS TIME PERIOD IS PERMITTED. If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for ex parte reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) ☐ by Treasury check or,
- b) ☐ by credit to Deposit Account No. _____, or
- c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

Michael J Hayes
Primary Examiner
Art Unit 3763

cc-Requester (if third party requester)
U.S. Patent and Trademark Office
PTO-471 (Rev. 04-01)

Office Action in Ex Parte Reexamination

Part of Paper No. 6

Reexamination

A substantial new question of patentability affecting claims 1, 2, 5, 9, 14, 15, 26, 28, 30-33, 36, 38, 40, 42-47, 49, 53, 56, 58, 59, 61, and 63 of United States Patent Number 5,697,536 is raised by the request for reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in reexamination proceedings are provided for in 37 CFR 1.550(e).

The request indicates that Requestor considers claims 1, 2, 5, 9, 14, 15, 26, 28, 30-33, 36, 38, 40, 42-47, 49, 53, 56, 58, 59, 61, and 63 are unpatentable over ROOS (U. S. Patent No. 4,116,198), *Über ein Instrument zur lockstromfreien transurethralen Resektion* (Elsasser and Roos article), PAO (U. S. Patent No. 4,805,616), PAO (U. S. Patent No. 4,674,499), DOSS (U. S. Patent No. 4,381,007), KAMERLING (U. S. Patent No. 5,217,459), or RYDELL (U. S. Patent No. 5,007,908).

The above new question of patentability is based solely on patents and/or printed publications already cited/considered in an earlier concluded examination of the patent being examined. On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 34 U.S.C. 303(a) and 312(a):

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis.

In the present instance, there exists a SNQ based solely on ROOS (U. S. Patent No. 4,116,198), *Über ein Instrument zur lektrostromfreien transurethralen Resektion* (Elsasser and Roos article), PAO (U. S. Patent No. 4,805,616), PAO (U. S. Patent No. 4,674,499), DOSS (U. S. Patent No. 4,381,007), KAMERLING (U. S. Patent No. 5,217,459), or RYDELL (U. S. Patent No. 5,007,908).

The old art listed above has been presented in a new light with a material new argument or interpretation.

Requestor's argument concerning the interpretation of the limitation of claim 1 of Roos ('198) (Exhibit A) of liquid providing electrical conductance between electrodes presents the old art in a new light. The declaration of Eberhard Roos (Exhibit 1) also presents old art Roos ('198) and the Elsasser and Roos article in a new light.

Old art Pao ('616), Pao ('499), Kamerling ('459), Doss ('007), and Rydell ('908) were cited in the prosecution of patent '536 or in reexamination 90/005601 (the reexamination of the '536 patent). Requestor's arguments, as presented in request for reexamination, received 5/07/03 presents this old art in a new light, with material new argument or interpretation as compared with its use in the earlier examinations.

Art Unit: 3763

Requestor's new arguments concerning the sterile salt solution disclosed by Pao ('616) and its inherent properties presents the art in a new light.

Requestor presents materially new arguments with respect to Pao '499 disclosure of introducing saline to the electrosurgical site and the saline's inherent property of conduction.


Requestor's new arguments concerning the saline presence at the electrodes site and its ability to help generate a current flow path with respect to Kamerling ('459) presents a materially new argument.

Pao '499, Doss ('007), and Rydell ('908) were cited in examination of patent '536, but their relevance to patentability of the claims was not discussed so reexamination based on these prior art is proper. See MPEP § 2242 (A)(2).

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a), to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 5,697,536 throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday - Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh
27 June 2003


MICHAEL J. HAYES
PRIMARY EXAMINER

Substantive Form PTO-1449 (Modified) Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR 51.08(b))	U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 00167-486001	Application No.
	Applicant Philip E. Eggers et al.			
	Filing Date November 18, 1996		Group Art Unit	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
MJEH	AA	4,116,198	09/26/1978	Roos	128	303.15	
	AB	4,381,007	04/26/1983	Doss	128	303.1	
	AC	4,674,499	06/23/1987	Pao	128	303.14	
	AD	4,803,616	02/21/1989	Pao	128	303.7	
	AE	5,007,908	04/16/1991	Rydell	606	47	
MJEH	AF	5,217,459	06/04/1993	Kamertling	606	48	
	AG						
BDOBS	AH						
	AI						
	AJ						
	AK						

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
BDOBS	AL						Yes	No
	AM							
	AN							
	AO							
	AP							

Other Documents (Include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
MJEH	AQ	Roos, Elzasser E., "An instrument for transurethral resection without leakage of current", <i>Medizinal-Markt/Acta Medico-technica</i> , Vol. 24, No. 4, 1976, pgs. 129-134.
MJEH	AR	Translation of Ref. AQ
	AS	
	AT	

Examiner Signature <i>Michael M. Hye</i>	Date Considered 6/28/03
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substantive Disclosure Form (PTO-1449)

**These pages have been removed from the
non-confidential appendix due to confidential
designations**

A 18275 - 18282

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of March, 2004, a true and correct copy of the
**SMITH & NEPHEW'S MOTION FOR RECONSIDERATION OF ORDERS
GRANTING ARTHROCARE'S MOTION TO DISMISS SMITH & NEPHEW'S
ANTITRUST COUNTERCLAIM AND GRANTING ARTHROCARE'S MOTION
FOR PERMANENT INJUNCTION** was caused to be served on the attorneys of record
at the following addresses as indicated:

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Attorney for Plaintiff/Counterclaim
Defendant
Ethicon, Inc.


William J. Marsden, Jr.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

FILED
CLERK U.S. DISTRICT COURT
DISTRICT OF DELAWARE
2004 APR -6 PM 4:25

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

**SMITH & NEPHEW'S UNOPPOSED MOTION TO LIFT STAY TO PERMIT
SMITH & NEPHEW TO FILE AN ANSWERING BRIEF IN OPPOSITION TO
ARTHROCARE'S MOTION TO DISMISS SMITH & NEPHEW'S ANTITRUST
COUNTERCLAIM**

Defendant, Smith & Nephew, Inc. ("Smith & Nephew") hereby moves to lift the stay previously imposed by the Court and permit Smith & Nephew to file an Answering Brief in opposition to the motion filed by ArthroCare Corp. ("ArthroCare") to dismiss Smith & Nephew's antitrust counterclaim. ArthroCare states that it does not oppose this motion. In support of this motion, Smith & Nephew states as follows:

1. On May 27, 2003, ArthroCare filed a Motion to Dismiss Smith & Nephew's Antitrust Counterclaim. (D.I. 429, "Motion to Dismiss"). Thereafter, on June 9, 2003, before Smith & Nephew's answering brief was due, the Court held a telephone conference to set a briefing schedule for all post-trial motions in this case. (D.I. 447).

2. During that June 9, 2003 teleconference, with respect to all matters relating to the issues of antitrust, damages and willfulness, the Court stayed all further proceedings, including briefing with respect to the Motion to Dismiss. (*Id.* at 10:15-22, 14:21-23, 15:2-5, 15:21-16:1). The Court also advised the parties that no formal order would issue because the orders staying the various issues discussed during the teleconference would be reflected in the transcript. (*Id.* at 12:21-24).

3. No further order has ever issued which lifted or otherwise addressed the Court's stay of any further briefing with respect to ArthroCare's Motion to Dismiss.

4. On March 10, 2004 the Court issued Orders (D.I. 482 and 484) in which the Court granted ArthroCare's Motion to Dismiss, as well as its motion for a permanent injunction. ("Motion for Permanent Injunction") (D.I. 424).¹

5. In the memorandum opinion supporting the Court's Order granting the Motion to Dismiss, the Court inferred from the absence of an answering brief filed by Smith & Nephew that the motion was not opposed: "Smith & Nephew has not responded... [t]he court, therefore, presumes that Smith & Nephew does not oppose the

¹ Defendant Smith & Nephew has filed a motion pursuant to Local Rule 7.1.5 for reconsideration (D.I. 488) because the Order granting the Motion to Dismiss was based on two mistaken assumptions: 1) that the motion was unopposed; and 2) that the viability of Smith & Nephew's antitrust counterclaim depends on a showing that this action was objectively baseless "sham" litigation. Because the erroneous dismissal of Smith & Nephew's antitrust counterclaims was the predicate for the court's finding that "it is not premature to enter an injunction" (D.I. 483 at 90, n.29), Smith & Nephew also requested reconsideration of the court's Order granting the Motion for Permanent Injunction. The injustice of the ruling on the antitrust counterclaim was compounded when ArthroCare ignored the Court's stay of briefing in opposing the motion for reconsideration and instead repeated its arguments in support of its motion to dismiss, knowing that Smith & Nephew again would have no opportunity to respond. Local Rule 7.1.5 ("The Court will determine from the motion and answer whether reargument will be granted."); *Stairmaster Sports/Medical Products, Inc. v. Groupe Procycle, Inc.*, 25 F.Supp.2d 270, 292 (D. Del. 1998) (Local Rule 7.1.5 "permits filing of only one brief per side with an emphasis on brevity ... StairMaster, apparently anxious to get the last word, filed a reply brief while Local Rule 7.1.5 distinctly sets out that 'the Court will determine from the motion and answer whether argument will be granted.'").

motion." (D.I. 483, at n. 1). This presumption was in error. Smith & Nephew made its opposition to the Motion to Dismiss known when it opposed the Motion for Permanent Injunction, as the Court acknowledged. (*Id.*). It was given no further opportunity to oppose because the Court stayed briefing on the Motion to Dismiss and all other activity related to the antitrust counterclaim.

6. Moreover, because the Court did not have a brief in opposition to the Motion to Dismiss, it adopted ArthroCare's misleading, incomplete and erroneous characterization of the counterclaim as a simple "sham" litigation claim and found it barred by the jury's verdict and the *Noerr-Pennington* doctrine. In particular, the Court characterized Smith & Nephew's antitrust counterclaim as "premised on the idea that ArthroCare and Ethicon² filed 'sham' litigation against Smith & Nephew to prevent or restrain it from entering the arthroscopic surgery market." Undoubtedly, this incomplete and inaccurate characterization of the antitrust counterclaim was derived in large part from the unanswered arguments made in ArthroCare's brief in support of its Motion to Dismiss. (D.I. 430). For example, ArthroCare argued there that, "Smith & Nephew had to make these allegations [that the lawsuit was objectively baseless] because ArthroCare's patent infringement suit *cannot give rise to antitrust liability unless* Smith & Nephew pleads and proves that ArthroCare has engaged in 'sham litigation.'" (D.I. 430 at 6). (emphasis added). However, Smith & Nephew's antitrust counterclaim is not so limited.

7. Fundamental fairness, as well as due process, requires that Smith & Nephew be given an opportunity to be heard on the merits in connection with the Motion to Dismiss. *Dougherty v. Harper's Magazine Co.*, 537 F.2d 758 (3d Cir. 1976). In *Dougherty*, the court stated:

Rule 12(d), FRCP requires that a Rule 12(b)(6) motion for dismissal ... may be disposed of only after a hearing, which affords an opportunity to present legal arguments either orally, in writing, or both at the District Court's discretion. The right to hearing is "the essence of our judicial

² Ethicon, Inc. is not a plaintiff in this case. Ethicon was added as a counterclaim defendant on the antitrust counterclaim included in the Amended Answer and Counterclaims of Smith & Nephew, Inc. (D.I. 219).

system, and the judge's feeling that the case is probably frivolous does not justify bypassing that right." ... In *Jordan v. County of Montgomery, Pennsylvania*, ... we held that an order dismissing a complaint under Rule 12(b)(6), entered without affording the plaintiff an opportunity to be heard, must be reversed. We note that in *Council of Federated Organizations v. Mize*, 339 F.2d 898 (5th Cir. 1964), the Court characterized as a denial of due process the entry of an order dismissing the complaint for failure to state a claim without giving the plaintiff an opportunity to be heard.

Id. at 761 (internal citations omitted). Similarly, the Supreme Court has held:

Under Rule 12(b)(6), a plaintiff with an arguable claim is ordinarily accorded notice of a pending motion to dismiss for failure to state a claim and an opportunity to amend the complaint before the motion is ruled upon. These procedures alert him to the legal theory underlying the defendant's challenge, and enable him meaningfully to respond by opposing the motion to dismiss on legal grounds or by clarifying his factual allegations so as to conform with the requirements of a valid legal cause of action. This adversarial process also crystallizes the pertinent issues and facilitates appellate review of a trial court dismissal by creating a more complete record of the case.

Neitzke v. Williams, 490 U.S. 319, 329-30 (1989).

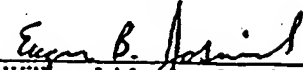
Conclusion

8. For the reasons set forth herein, Smith & Nephew respectfully requests that the Court lift its June 9, 2003 stay with respect to briefing on ArthroCare's Motion to Dismiss, and allow Smith & Nephew to file an Opposition to the Motion.

Dated: April 6, 2004

FISH & RICHARDSON P.C.

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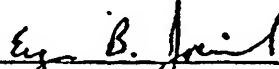
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SMITH & NEPHEW, INC.

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RULE 7.1.1 CERTIFICATE

I hereby certify that I have contacted counsel for ArthroCare on the matters set forth in the Motion. I further certify that I ArthroCare's counsel does not oppose our motion to lift the stay to permit Smith & Nephew to file an answering brief.



Eugene B. Joswick

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

PROPOSED ORDER

The Court having considered Smith & Nephew's Unopposed Motion to Lift Stay to Permit Smith & Nephew to File an Answering Brief in Opposition to ArthroCare's Motion to Dismiss Smith & Nephew's Antitrust Counterclaim,

IT IS HEREBY ORDERED this _____ day of _____, 2004 that:

Smith & Nephew's Unopposed Motion to Lift Stay to Permit Smith & Nephew to File an Answering Brief in Opposition to ArthroCare's Motion to Dismiss Smith & Nephew's Antitrust Counterclaim is granted.

United States District Judge

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of April, 2004, a true and correct copy of the SMITH & NEPHEW'S UNOPPOSED MOTION TO LIFT STAY TO PERMIT SMITH & NEPHEW TO FILE AN ANSWERING BRIEF IN OPPOSITION TO ARHTROCARE'S MOTION TO DISMISS SMITH & NEPHEW'S ANTITRUST COUNTERCLAIM was caused to be served on the attorneys of record at the following addresses as indicated:

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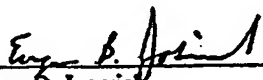
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Ethicon, Inc.



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US005697882A

United States Patent [19]

Eggers et al.

[11] Patent Number: 5,697,882

[45] Date of Patent: Dec. 16, 1997

[54] SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION[75] Inventors: Philip E. Eggers, Dublin, Ohio; Hira
V. Thapliyal, Los Altos, Calif.[73] Assignee: Arthrocare Corporation, Sunnyvale,
Calif.

[21] Appl. No.: 561,958

[22] Filed: Nov. 22, 1995

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 445,219, Jan. 7, 1993,
which is a continuation-in-part of Ser. No. 59,681, May 10,
1993, abandoned, which is a continuation-in-part of Ser. No.
958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a
continuation-in-part of Ser. No. 817,575, Jan. 7, 1992,
abandoned.[51] Int. Cl.⁶ _____ A61B 1/00

[52] U.S. Cl. _____ 604/114; 604/22

[58] Field of Search _____ 604/114, 22, 28,
604/49, 113, 41; 606/27-32, 35, 38, 41

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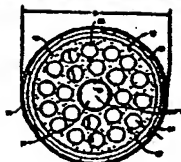
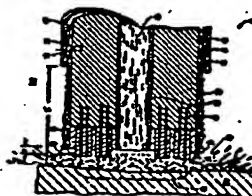
Primary Examiner—Manuel Meadez

Attorney, Agent, or Firm—Townsend and Townsend and
Crew LLP

[57] ABSTRACT

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (58) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (63) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the return electrode and the electrode array so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the active and return electrodes.

56 Claims, 17 Drawing Sheets



Joint
Trial Exhibit
JTX 2
C.A. No. 95-306-SLR

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				5,569,242	10/1996	Lax et al.	606/42

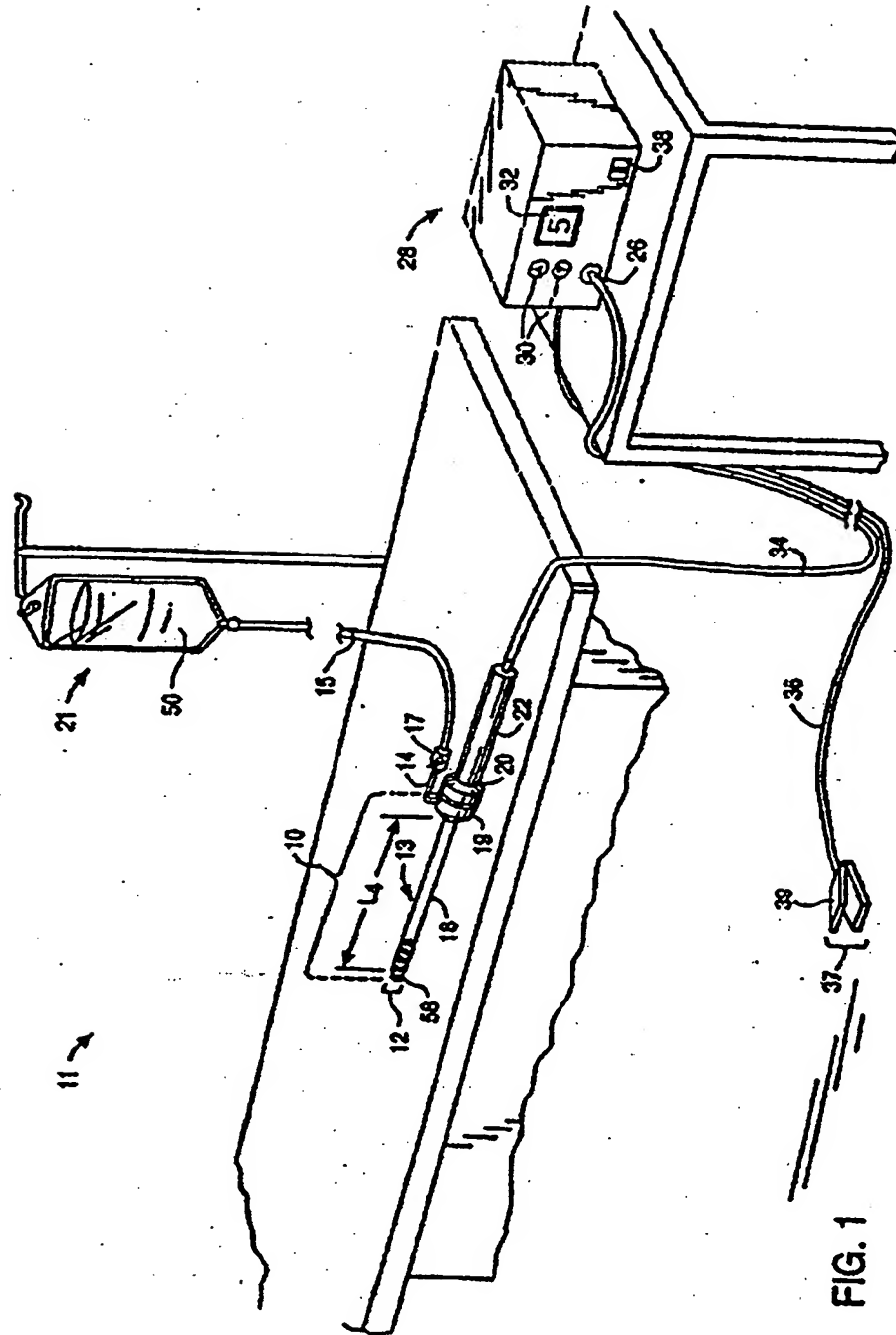


FIG. 1

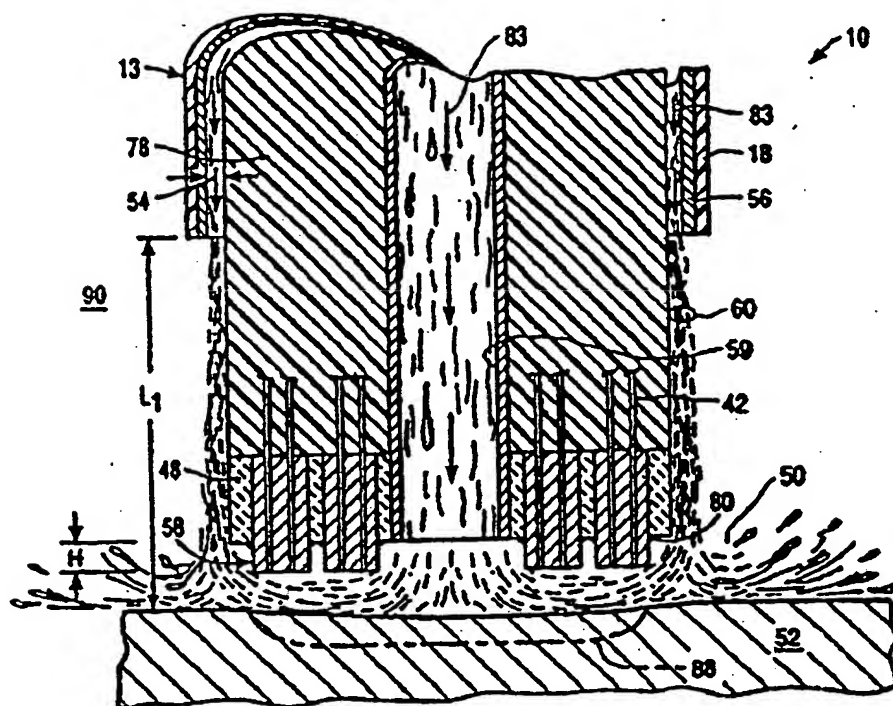


FIG. 2A

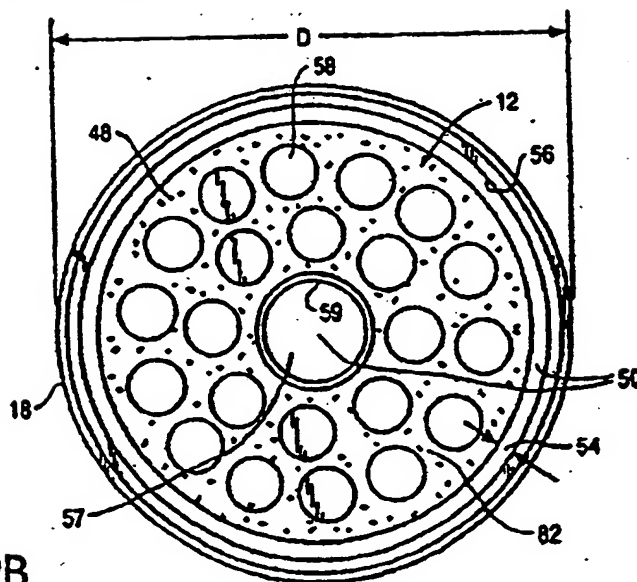


FIG. 2B

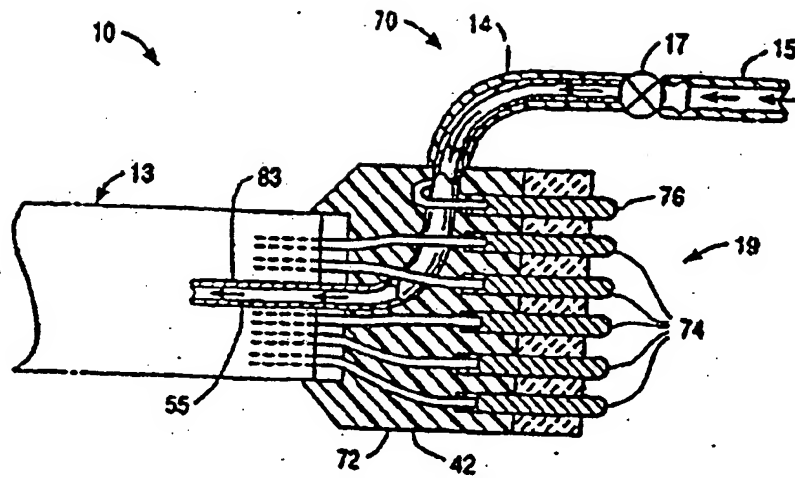


FIG. 2C

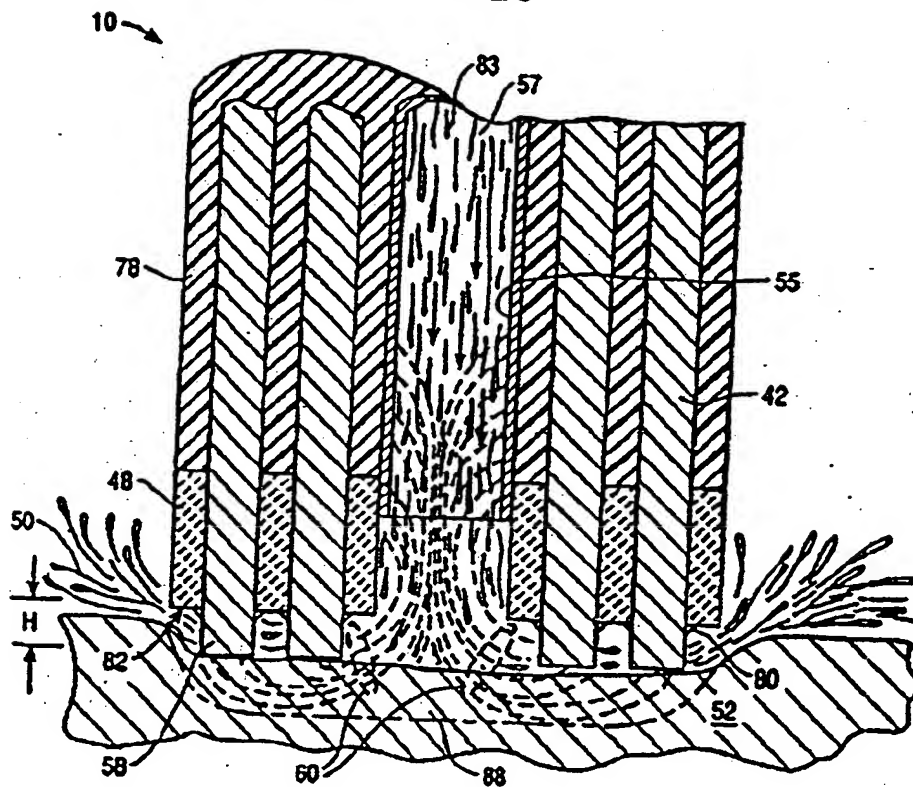


FIG. 3

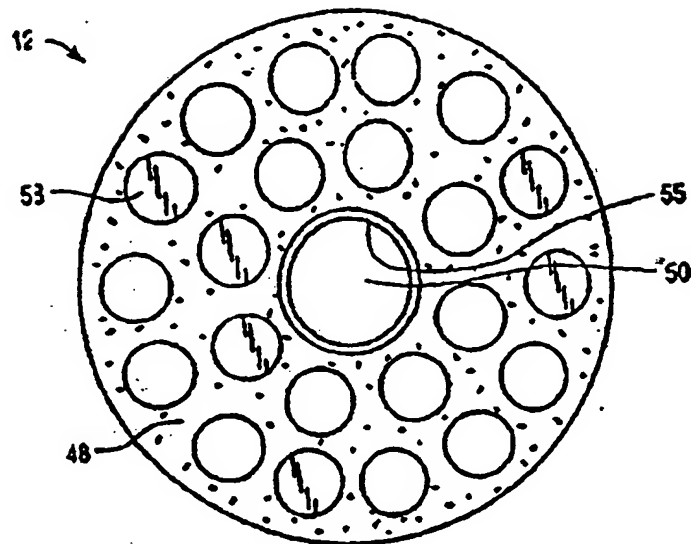


FIG. 4

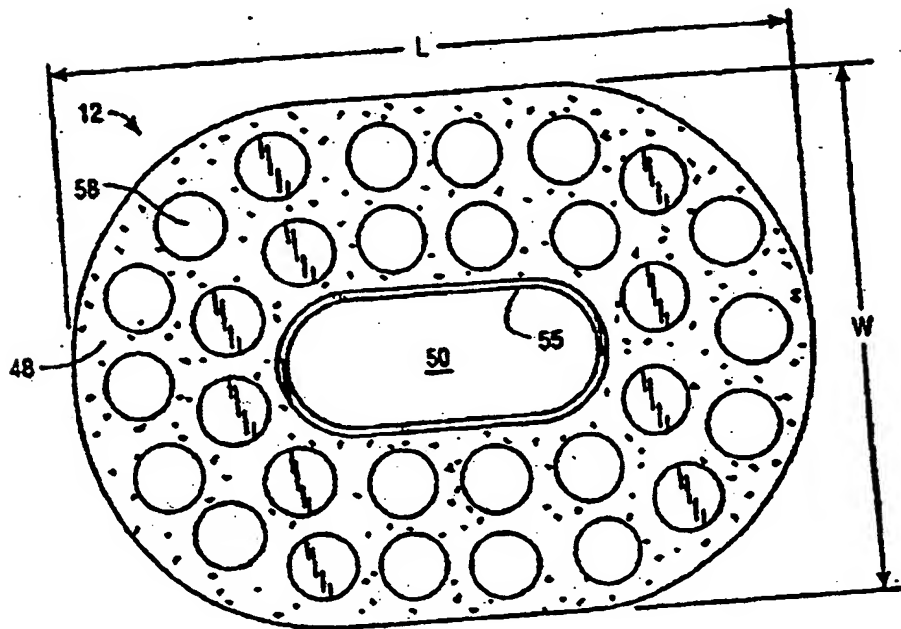


FIG. 5

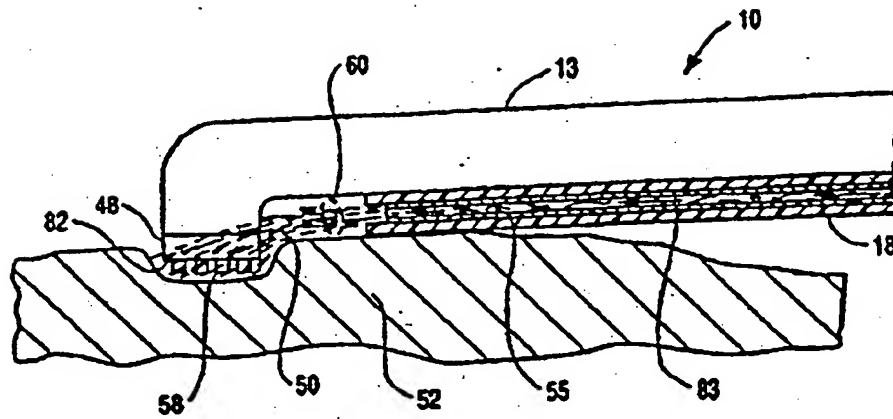


FIG. 6

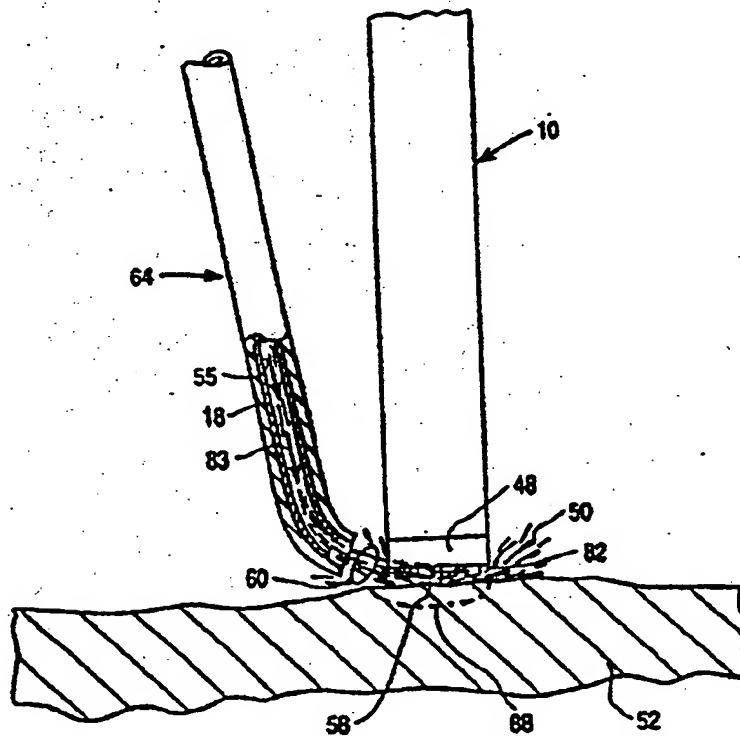


FIG. 7

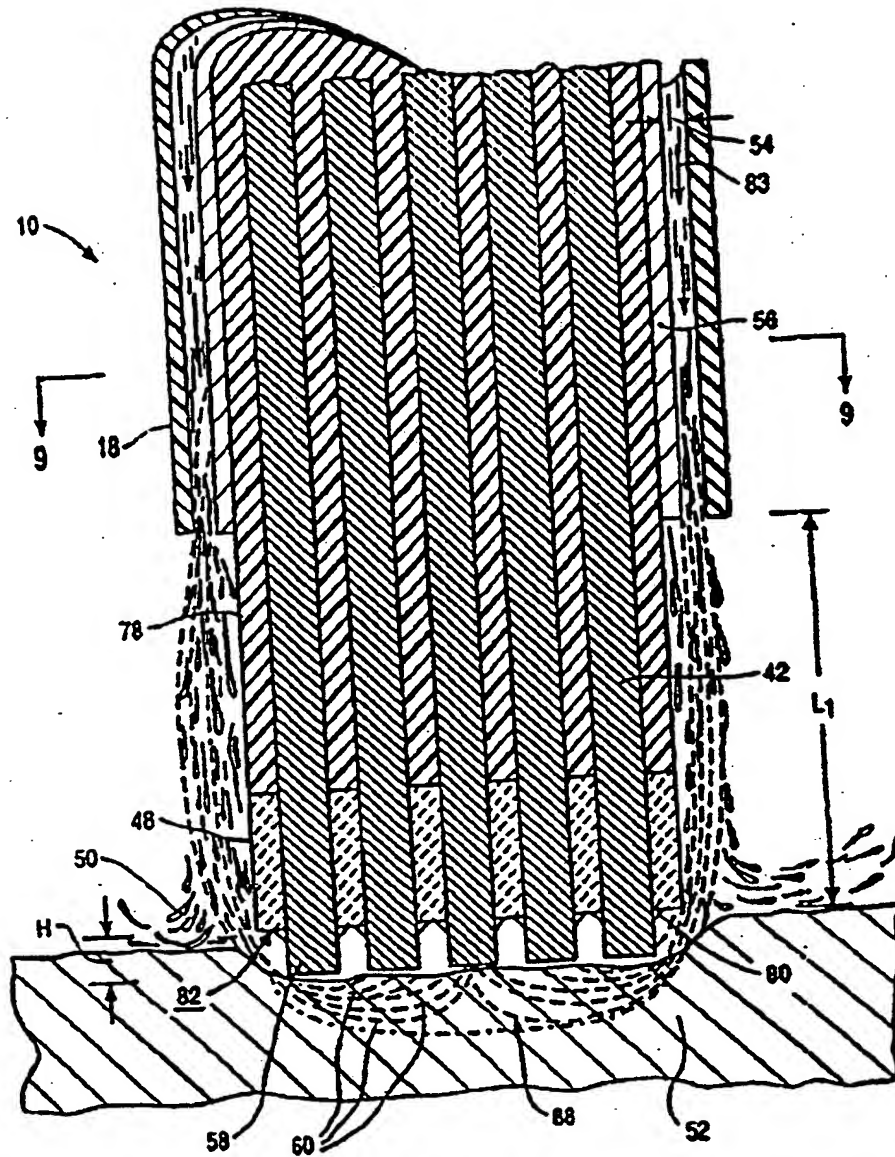


FIG. 8

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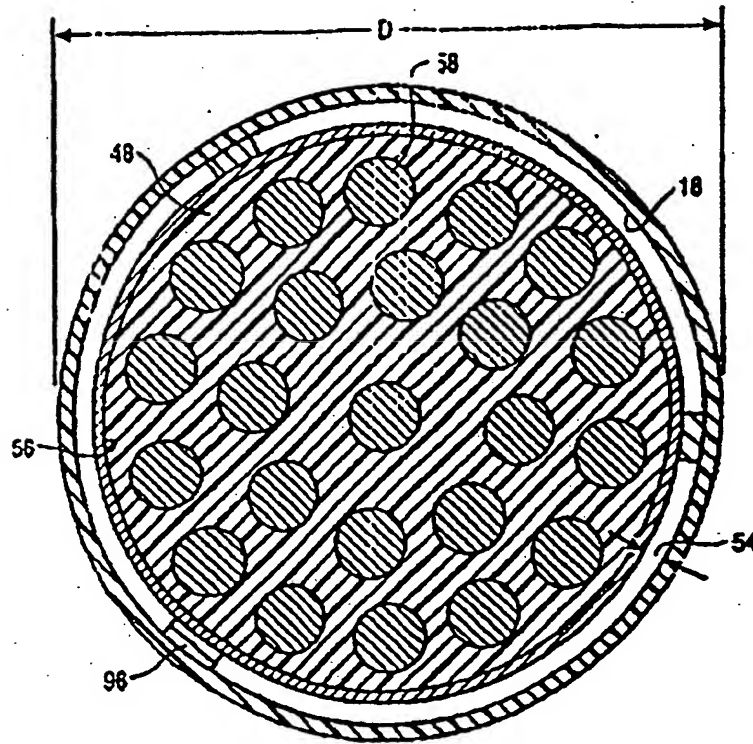


FIG. 9

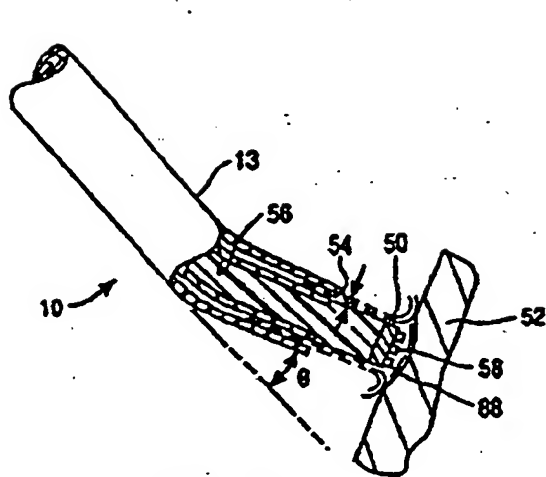


FIG. 10

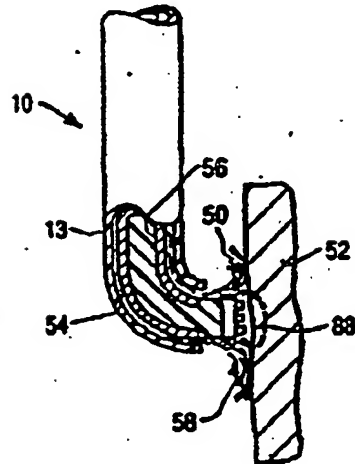


FIG. 11

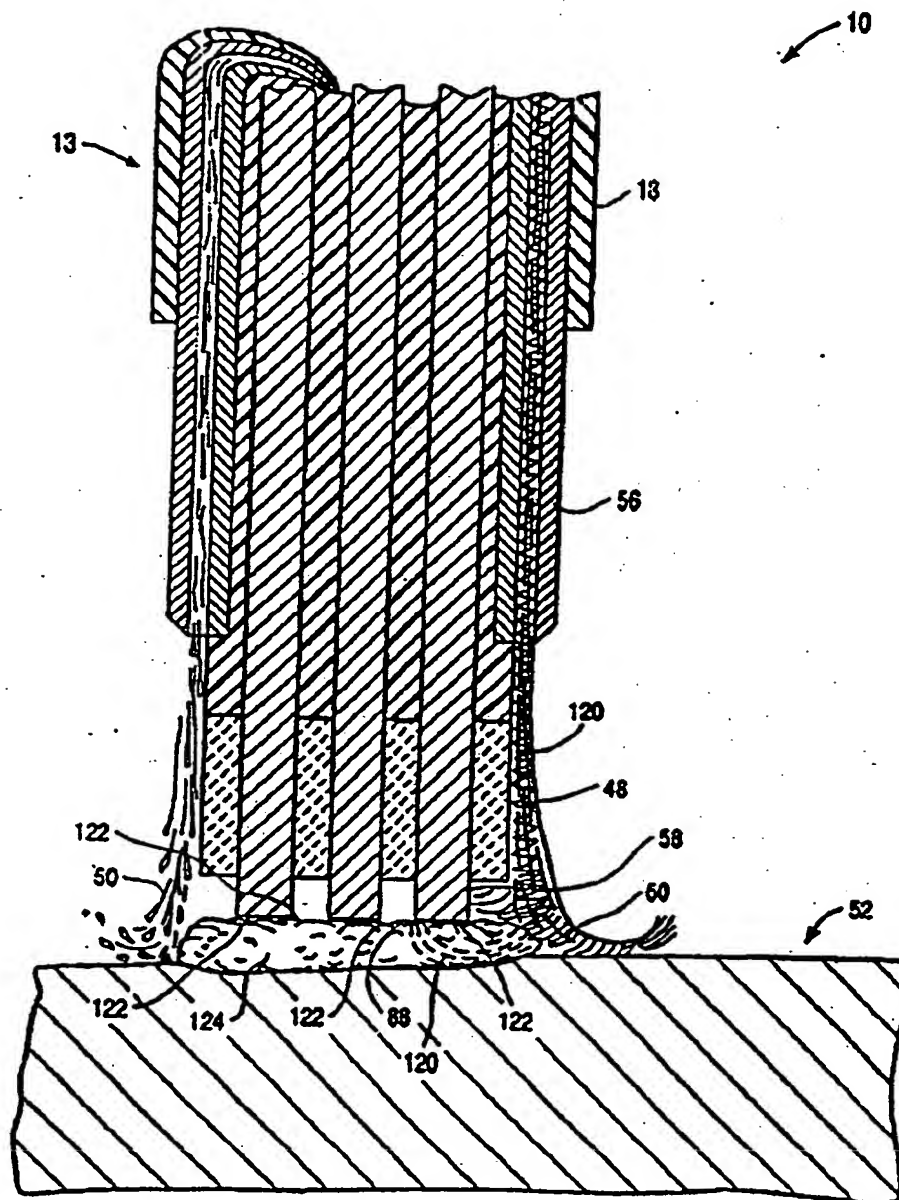


FIG. 15

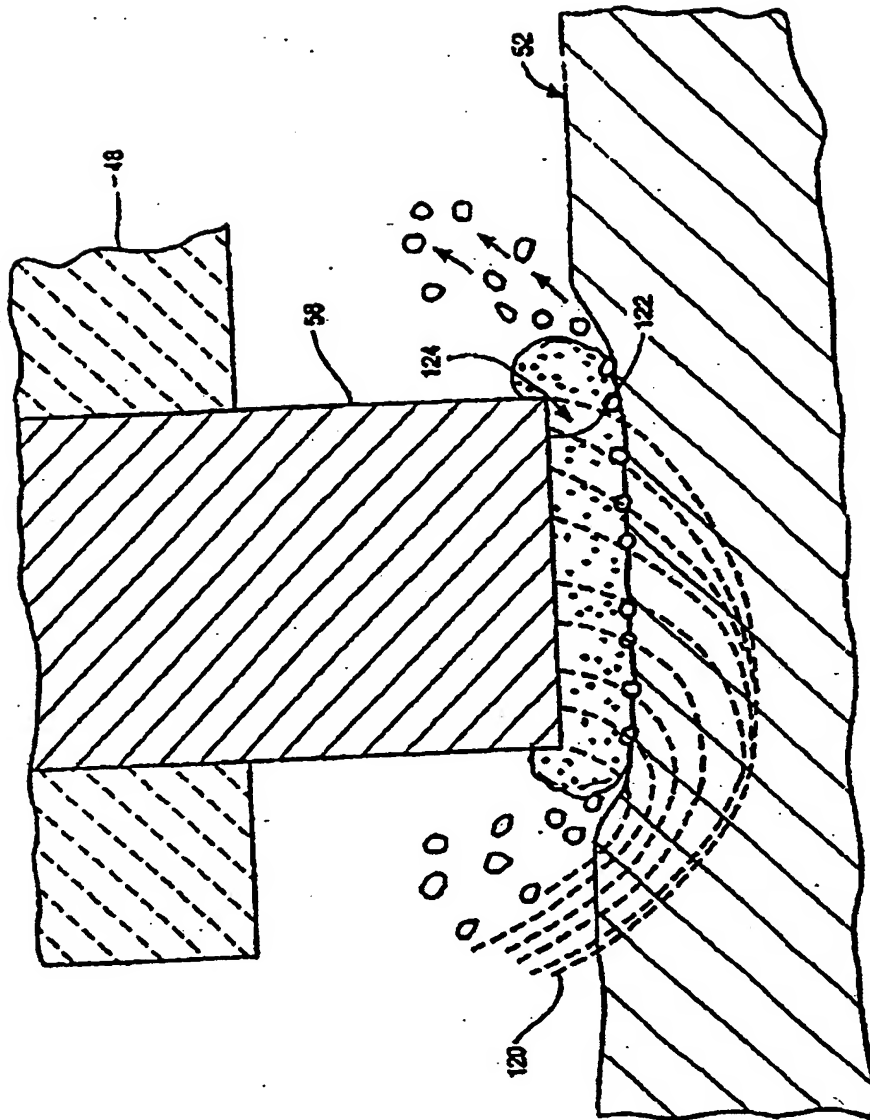


FIG. 16

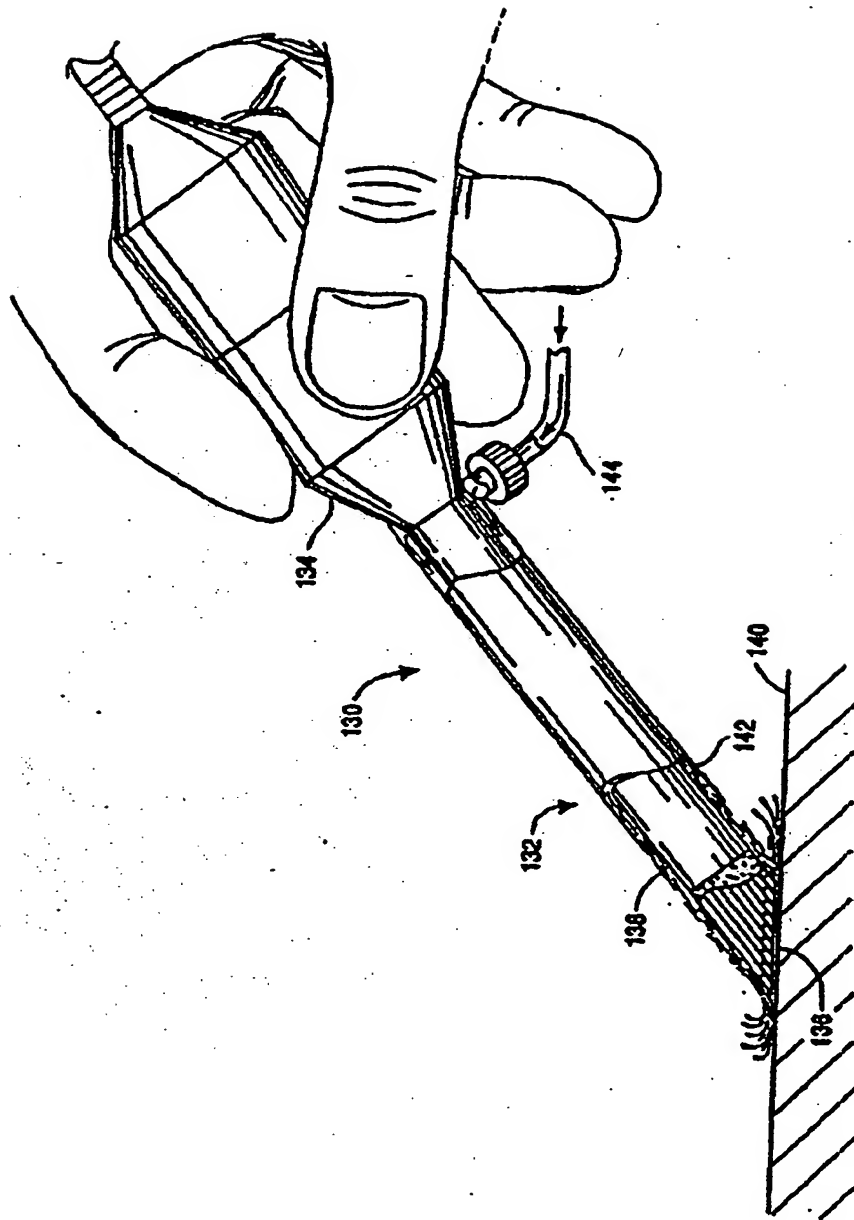


FIG. 17

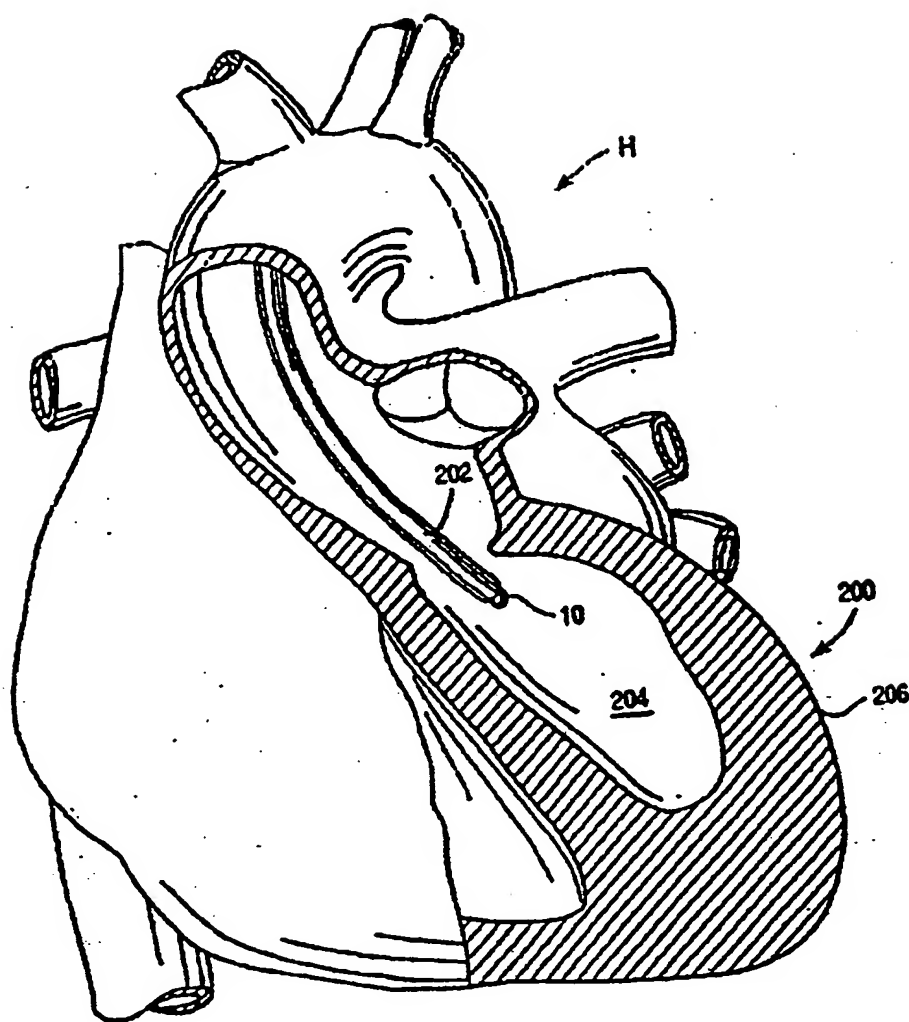


FIG. 18

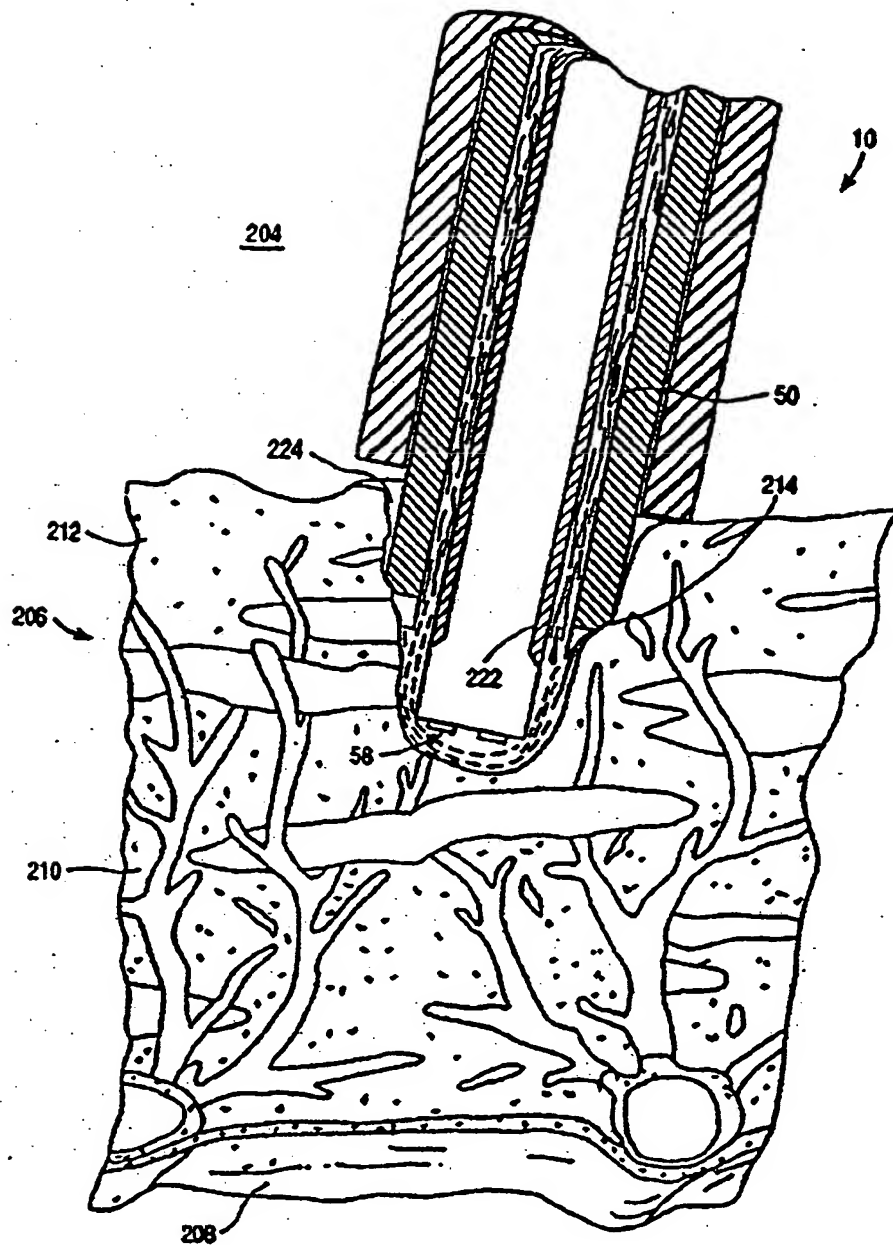


FIG. 19

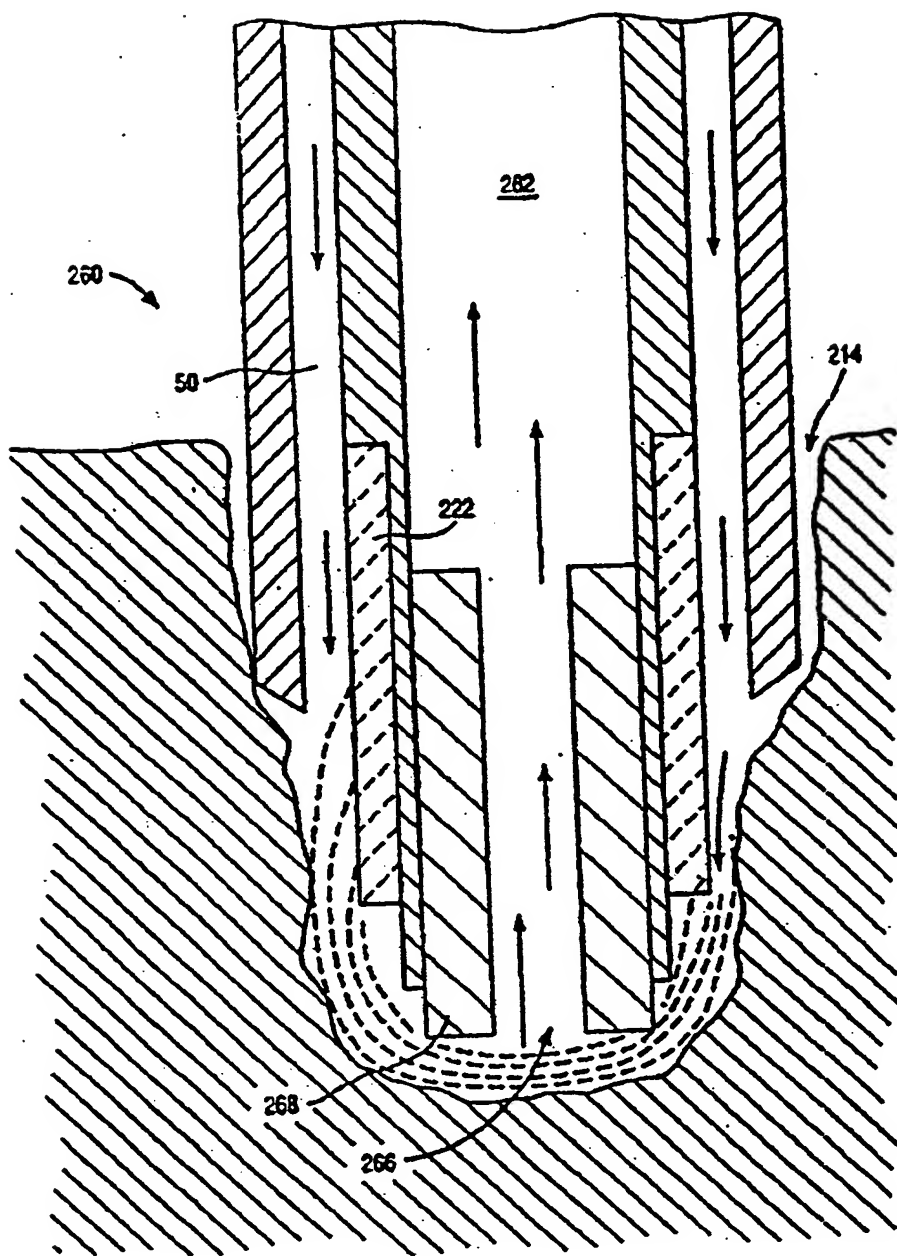


FIG. 20

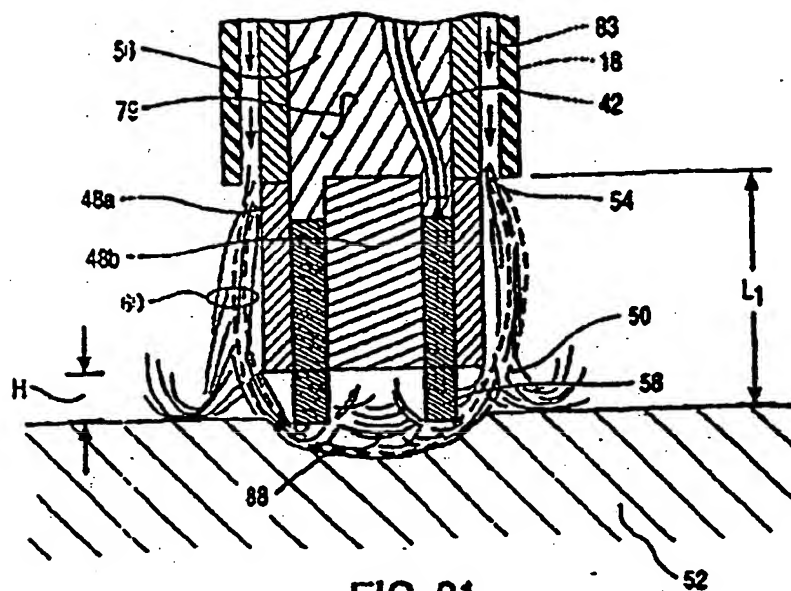


FIG. 21

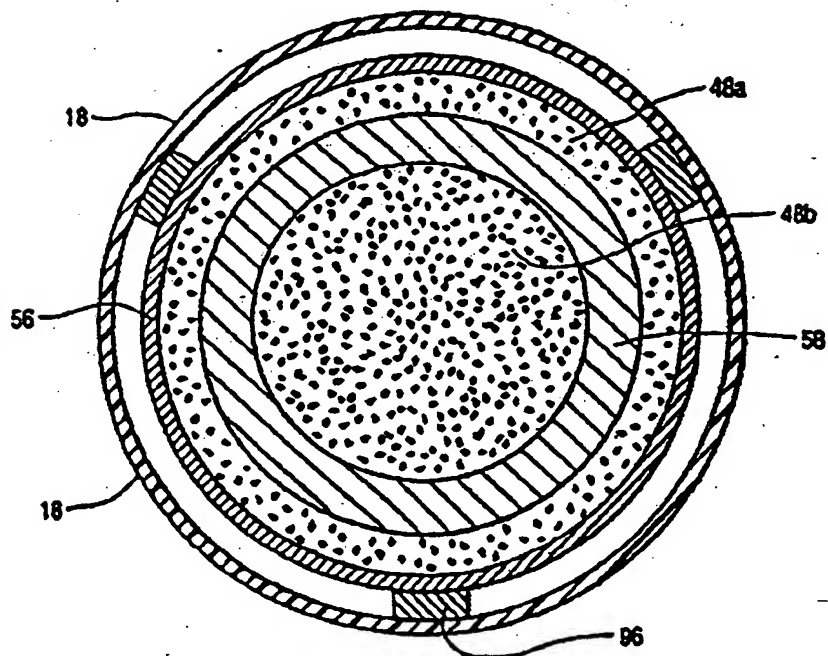


FIG. 22

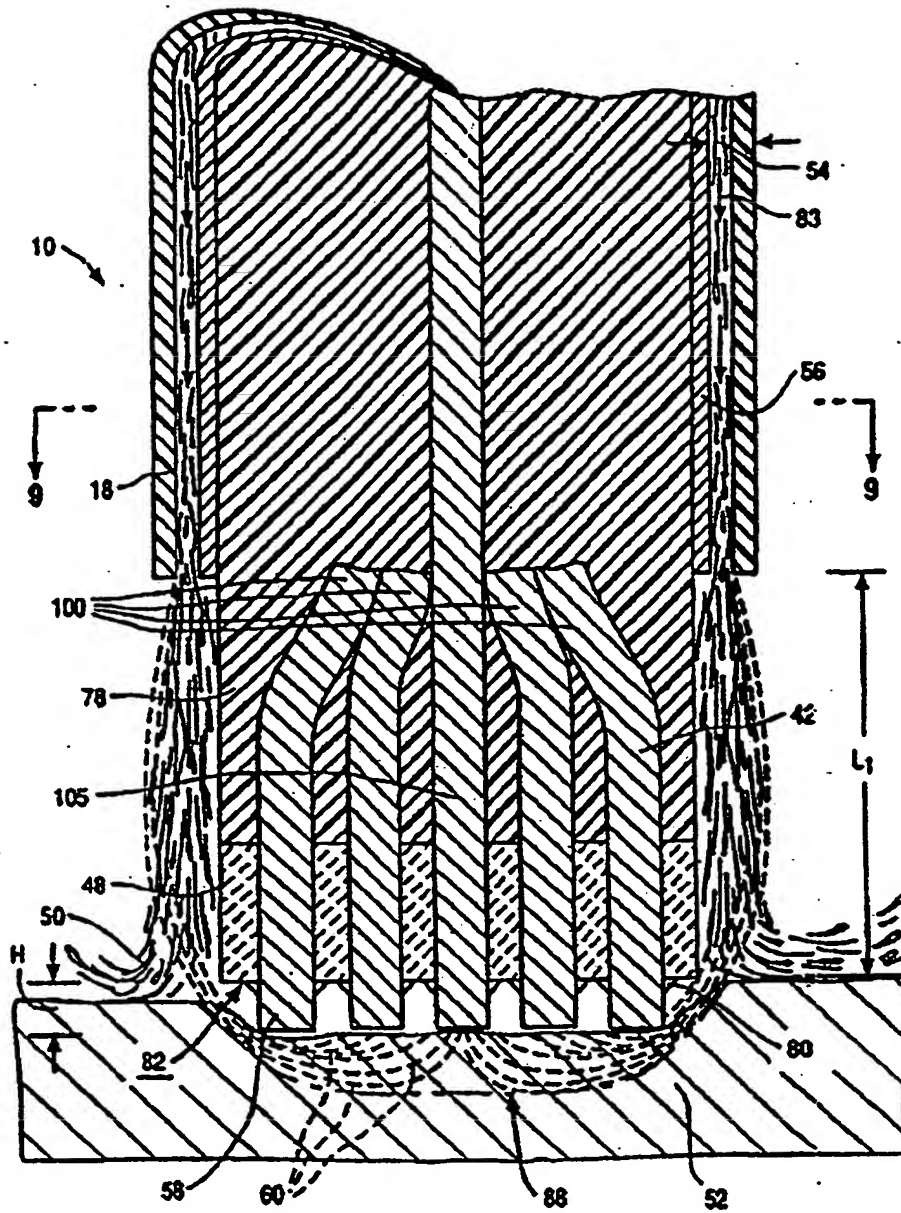


FIG. 23

A 18618

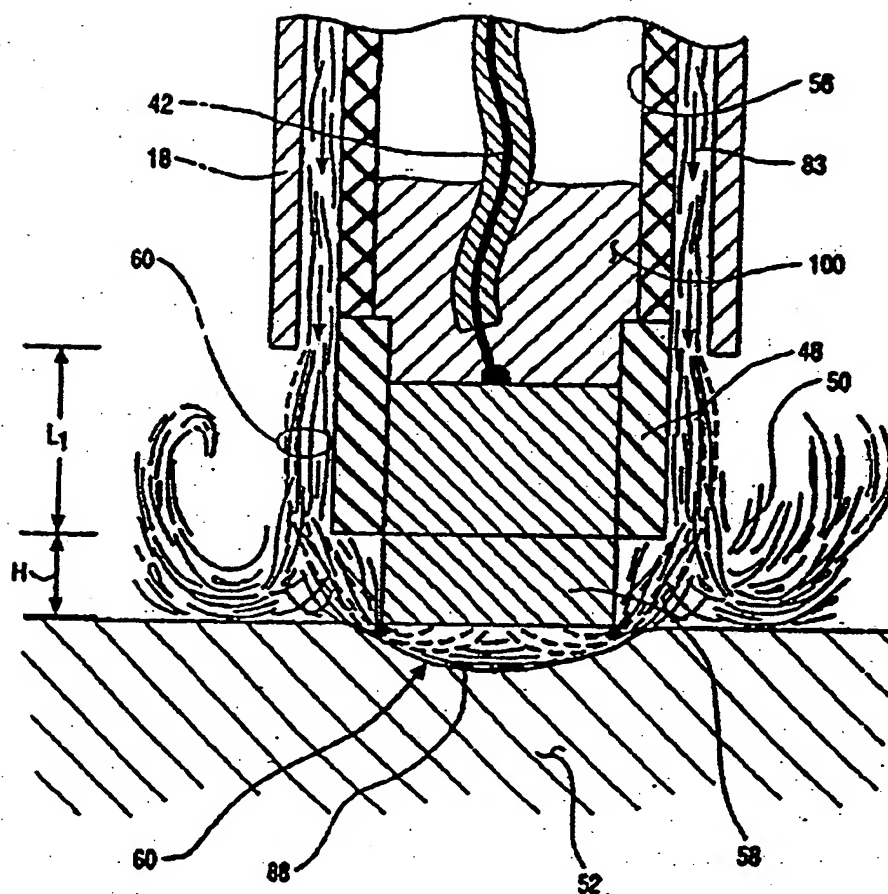


FIG. 24

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

The present invention is a continuation-in-part of application Ser. No. 08/485,219, filed on Jun. 7, 1995 and still pending, which was a continuation-in-part of PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993 and now abandoned, which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992 now U.S. Pat. No. 5,366,443, which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992 now abandoned, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger, that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point

with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for abating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as carbon lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric ablation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO₂ lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of

tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracoscopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent to the treatment site.

DESCRIPTION OF THE BACKGROUND ART

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Am. Surg.* 1:242-246 and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,221,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,453, 5,423,803, 5,102,410, 5,282,797, 5,290,273, 5,304,170, 5,312,395, 5,336,217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316, 4,658,817, 5,389,096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as scar or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity

to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrically conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the target tissue by a suitable distance during the ablation process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the

active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigated flooded environments, such as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return electrode.

The active and return electrodes will preferably be configured such that, upon the application of a sufficient high-frequency voltage, a thin layer of the electrically conducting liquid is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdowns (i.e., ionization) of ionizable species within the vapor layer or region and the emission of photons and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy

flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy flux.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmyocardial revascularization procedure;

FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmyocardial channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for cannulating or boring channels or holes through tissue, such as the ventricular wall during transmyocardial revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the cannalization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., tooth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance

characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdowns of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electrosurgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdowns of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable atoms and molecules, such as hydrogen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target

tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surface; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The photon energy produces photoablation through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photoablation is a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric breakdown of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces areas which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or region into the tissue, thereby minimizing joules heating in, and associated necrosis of, the tissue.

As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 10^{20} atoms/cm³, which corresponds to about 3×10^{-9} grams/cm³. Applicants also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 10^{20} atoms/cm³ for aqueous solutions), electron avalanche occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring in the region ahead of the front, viz. heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the inducement of energetic electrons and photons. The electrical conductivity of the fluid (in units of millisiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to cauterize and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes

having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and currents that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900 volts.

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art, the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to irreversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 nH to 50,000 nH, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically ceased and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating thereof.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 54 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support canals or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 29 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 36 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 3. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contacted within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid path 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-5, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid path 83 provides a pathway for electrical current flow between target tissue 82 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 43 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of return electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 18.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shunting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 104a, 104b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 104a and 104b as indicated by current flux lines 60 to heat the target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

other than the generally linear shape shown in FIGS. 1-6. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 16) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 16). A shaft having a 90° bend angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described above.

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or arc tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48a of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloy thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 100. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or crimp connection 100. In FIG. 24, an electrosurgical probe 10

comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photons and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensable gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentation, such as freckles, tanos, age or liver spots, birth marks, malignant melanomas, and superficial lesions in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodysplasia, e.g., skin angioma, malignant tumor tissue, hemangioma (i.e., tissue bulges extending from the vertebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an electro-surgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum lucidum and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmyocardial revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen enriched blood flowing into the ventricular cavity from the aorta to directly flow into the myocardium, rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electro-surgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electro-surgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedure. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 204, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

Electrically conducting liquid 58 is delivered through an annular lumen 228 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58, preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiment, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 58 to flow over the tissue surface being cauterized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 28 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 260 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an open distal end 264 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 264 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, the heart beat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole) of the heart.

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and positioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional means. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

What is claimed is:

1. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

2. The method of claim 1 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

3. The method of claim 2 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm².

4. The method of claim 2 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².

5. The method of claim 2 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0 mm.

6. The method of claim 2 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.

7. The method of claim 2 wherein the electrode terminals comprises a material with a relatively low thermal conductivity.

8. The method of claim 7 wherein the electrode materials comprises a material selected from the group consisting of titanium, magnesium, platinum, aluminum and tantalum.

9. The method of claim 2 wherein the return electrode has a distal end positioned proximal to the electrode array.

10. The method of claim 2 wherein the electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

11. The method of claim 2 wherein the electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

12. The method of claim 11 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

14. The method of claim 1 wherein at least a portion of the energy is in the form of energetic electrons.

15. The method of claim 14 wherein the energy of the energetic electrons is sufficient to cause dissociation or disintegration of molecules of the body structure.

16. The method of claim 14 wherein the energy evolved by the energetic electrons is greater than 3 eV.

17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.

18. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

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19. The method of claim 1 wherein the electrode terminal is positioned between 0.02 to 5 mm from the target site.

20. The method of claim 1 wherein the vapor layer has a thickness of about 0.02 to 2.0 mm.

21. The method of claim 1 wherein the distance between the most proximal portion of the electrode terminal and the most distal portion of the return electrode is in the range from 0.5 to 10 mm.

22. The method of claim 1 wherein the electrode terminal and the return electrode are of comparable size and comprise a bipolar array of isolated electrode terminals which both come in close proximity or in contact with the body structure.

23. The method of claim 1 wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 2 mS/cm.

24. The method of claim 1 wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.

25. The method of claim 1 wherein the electrode height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

26. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being in the range from 500 to 1400 volts peak to peak.

27. The method of claim 26 wherein the high frequency voltage is in the range from 700 to 900 volts peak to peak.

28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

29. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal; and inducing the discharge of photons to the target site in contact with the vapor layer.

30. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the active electrode surface; and inducing the discharge of energetic electrons to the target site in contact with the vapor layer.

31. The method of claim 28 wherein the depth of necrosis is 0 to 400 microns.

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32. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

33. The method of claim 32 wherein the generating step comprises:

providing a return electrode electrically coupled to a high frequency voltage source;

applying a high frequency voltage between the electrode terminal and the return electrode; and

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal.

34. The method of claim 33 further comprising developing a film layer of vapor between the active electrode and the body structure at the target site.

35. The method of claim 33 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

36. The method of claim 35 wherein the cooling step includes translating the distal surface of the electrode terminal over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

37. The method of claims 1 and 28 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

38. The method of claim 37 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

39. The method of claim 37 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.

40. The method of claim 37 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.

41. The method of claims 28 and 32 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

42. The method of claim 41 wherein the generating step comprises:

providing a return electrode electrically coupled to a higher frequency voltage source;

applying a high frequency voltage between the return electrode and the array of electrode terminals; and

vaporizing the electrically conducting fluid in a thin layer over one or more of the electrode terminals of the array.

43. The method of claim 42 further comprising developing a film layer of vapor between one or more of the electrode terminals and the target site.

44. The method of claim 42 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

45. The method of claims 1 and 33 wherein the density of the vapor layer is less than about 10^{20} atoms/cm³.

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46. The method of claims 1 and 30 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 1 and 28 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

48. The method of claims 26 and 28 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 26 and 28 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

50. The method of claims 26 and 28 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.

51. The method of claims 26 and 28 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

52. The method of claims 1 and 28 further comprising cooling the tissue with the electrically conducting fluid to

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reduce the temperature rise of those portions of the body structure adjacent the target site.

53. The method of claim 52 wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

55. The method of claims 1 and 28 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 26 and 28 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

• • • • •

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Phillip E. Eggers, et. al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

23. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode terminal in close proximity to the target site in the presence of an electrically conducting [terminal] fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Signed and Sealed this
Seventh Day of April, 1998

Attest:

Bruce Lehman

Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers et al.

Page 1 of 2

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

37. The method of claims 23 or 48 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

45. The method of claims 23 or 55 wherein the density of the vapor layer is less than about 10^{20} atoms/cm³.

46. The method of claims 23 or 50 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 23 or 48 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

48. The method of claims 48 or 52 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 48 or 52 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

50. The method of claims 48 or 52 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.

51. The method of claims 48 or 52 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers et al.

Page 2 of 2

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

52. The method of claims 23 or 48 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

54. The method of claims 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

55. The method of claims 23 or 48 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 48 or 52 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

Signed and Sealed this
Second Day of May, 2000

Attest:

Attesting Officer



Q. TODD DICKINSON

Director of Patents and Trademarks

A 18636

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 5,697,882

DATED : December 16, 1997

INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 24, lines 6-18, claim 1, should read as follows:

1. A method for applying energy to a target site on a patient body structure comprising:
 - providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
 - positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and
 - applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

This certificate supersedes Certificate of Correction issued April 7, 1998.

Signed and Sealed this
Twenty-fifth Day of August, 1998



Attest:

Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks



US005697882A

United States Patent [19]

Eggers et al.

[11] Patent Number: 5,697,882

[45] Date of Patent: Dec. 16, 1997

[54] SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
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Calif.

[21] Appl. No.: 561,958

[22] Filed: Nov. 22, 1995

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 485,219, Jun. 7, 1995,
which is a continuation-in-part of Ser. No. 59,681, May 10,
1993, abandoned, which is a continuation-in-part of Ser. No.
958,977, Oct. 9, 1992, Pat. No. 5,366,443, which is a
continuation-in-part of Ser. No. 817,575, Jan. 7, 1992,
abandoned.[51] Int. Cl.⁶ _____ A61B 1/00

[52] U.S. Cl. _____ 604/114; 604/22

[58] Field of Search _____ 604/114, 22, 28,
604/49, 113, 41; 606/27-32, 35, 38, 41

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Primary Examiner—Manuel Mendez

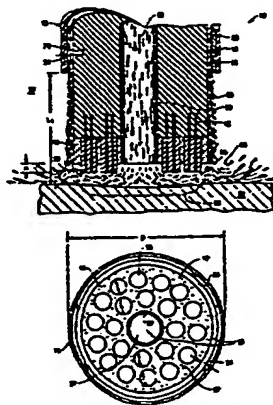
Attorney, Agent, or Firm—Townsend and Townsend and
Crew LLP

[57]

ABSTRACT

An electrosurgical probe (10) comprises a shaft (13) having an electrode array (58) at its distal end and a connector (19) at its proximal end for coupling the electrode array to a high frequency power supply (28). The shaft includes a return electrode (56) recessed from its distal end and enclosed within an insulating jacket (18). The return electrode defines an inner passage (83) electrically connected to both the return electrode and the electrode array for passage of an electrically conducting liquid (50). By applying high frequency voltage to the electrode array and the return electrode, the electrically conducting liquid generates a current flow path between the return electrode and the electrode array so that target tissue may be cut or ablated. The probe is particularly useful in dry environments, such as the mouth or abdominal cavity, because the electrically conducting liquid provides the necessary return current path between the active and return electrodes.

56 Claims, 17 Drawing Sheets



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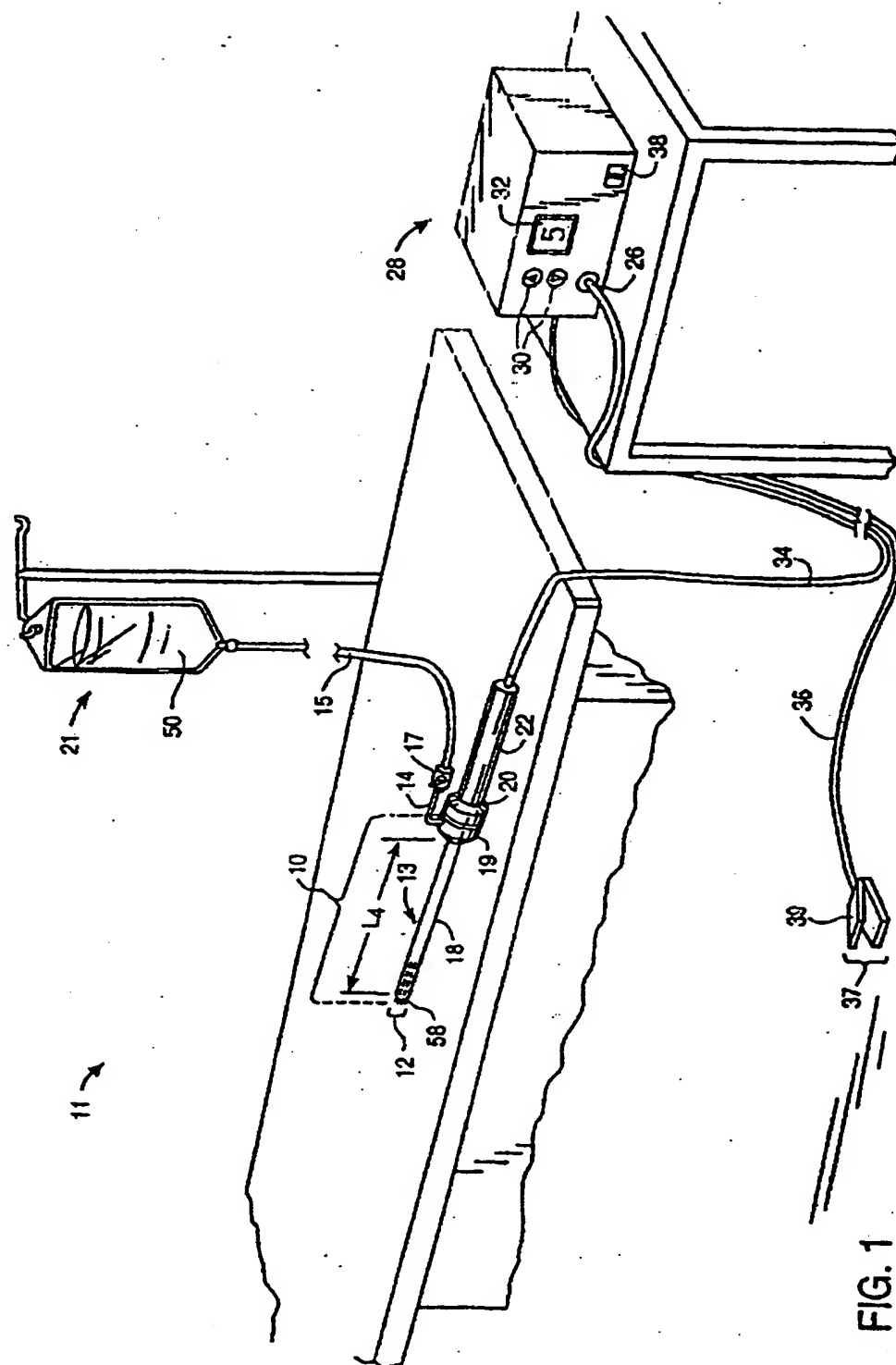


FIG. 1

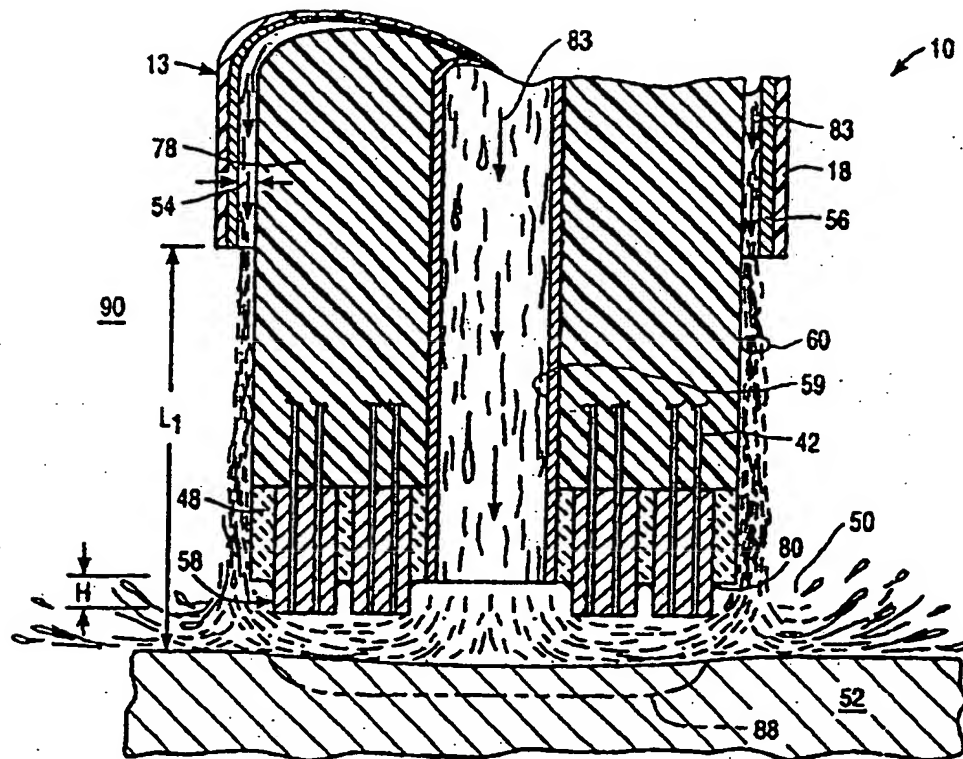


FIG. 2A

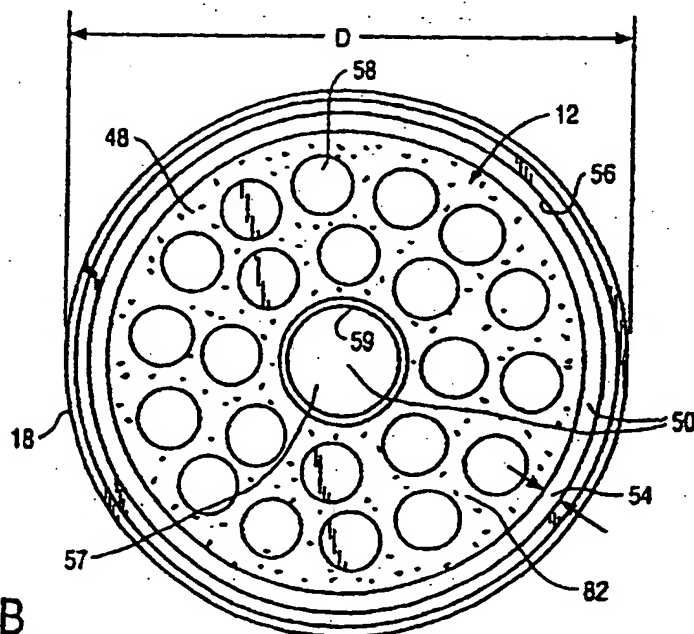


FIG. 2B

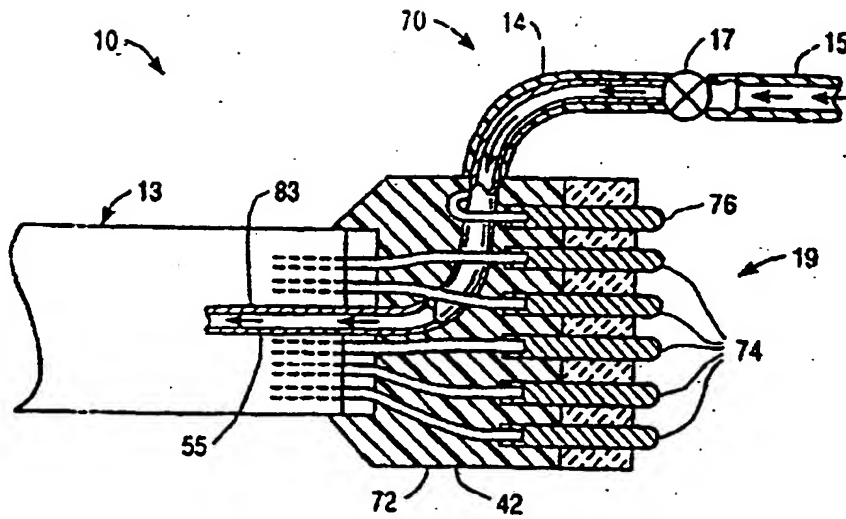


FIG. 2C

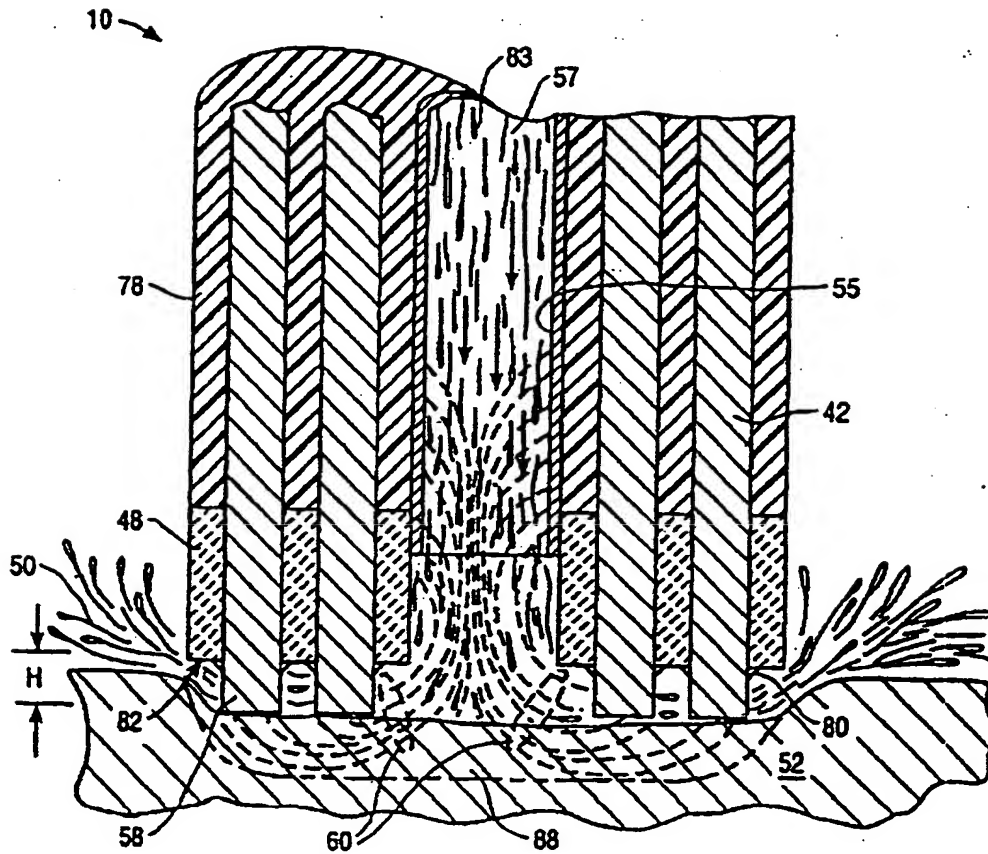


FIG. 3

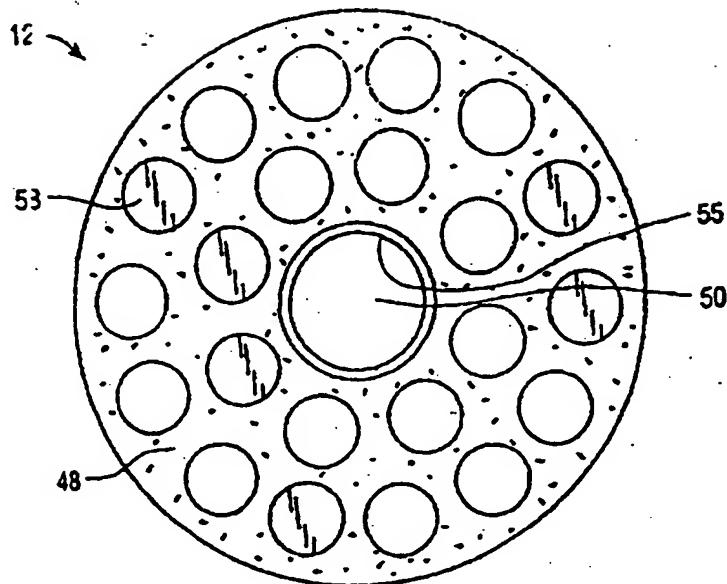


FIG. 4

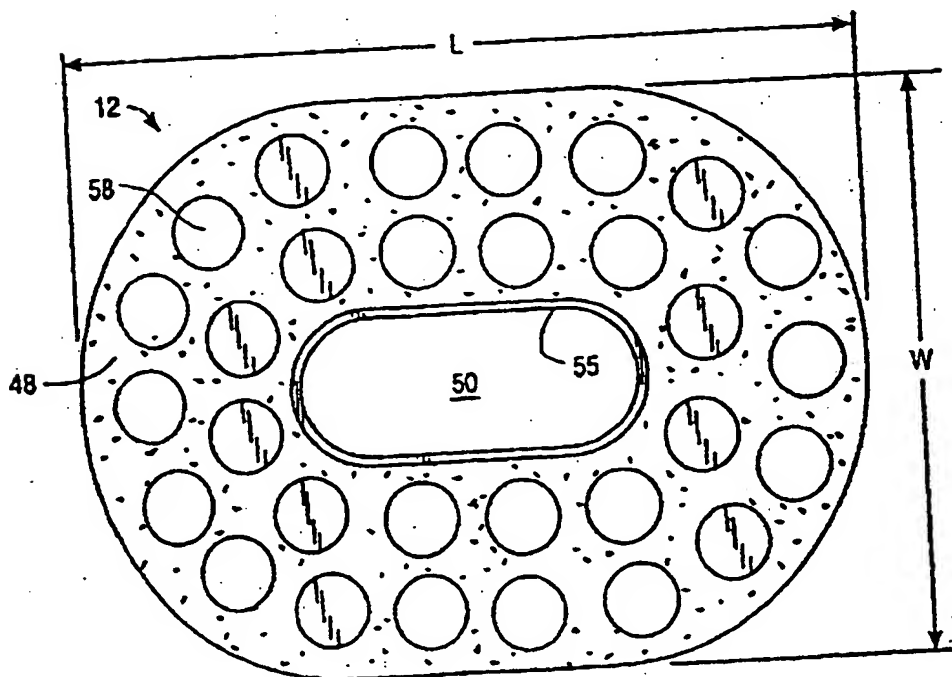


FIG. 5

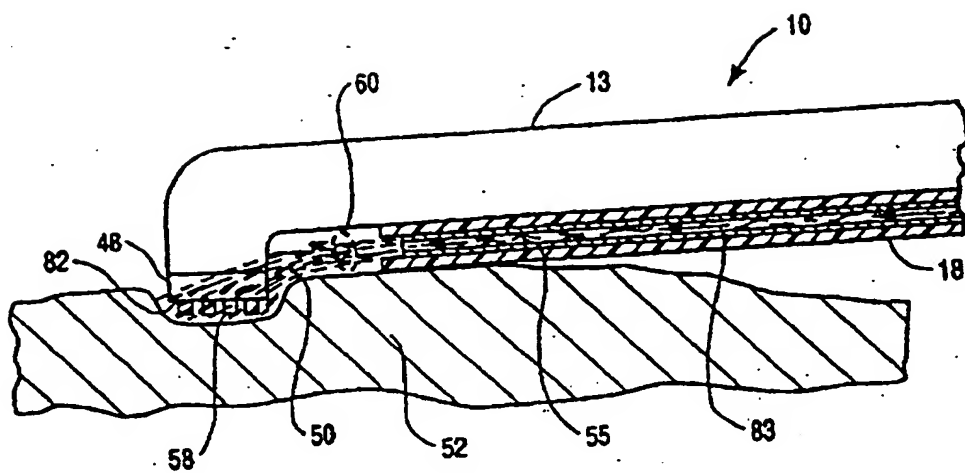


FIG. 6

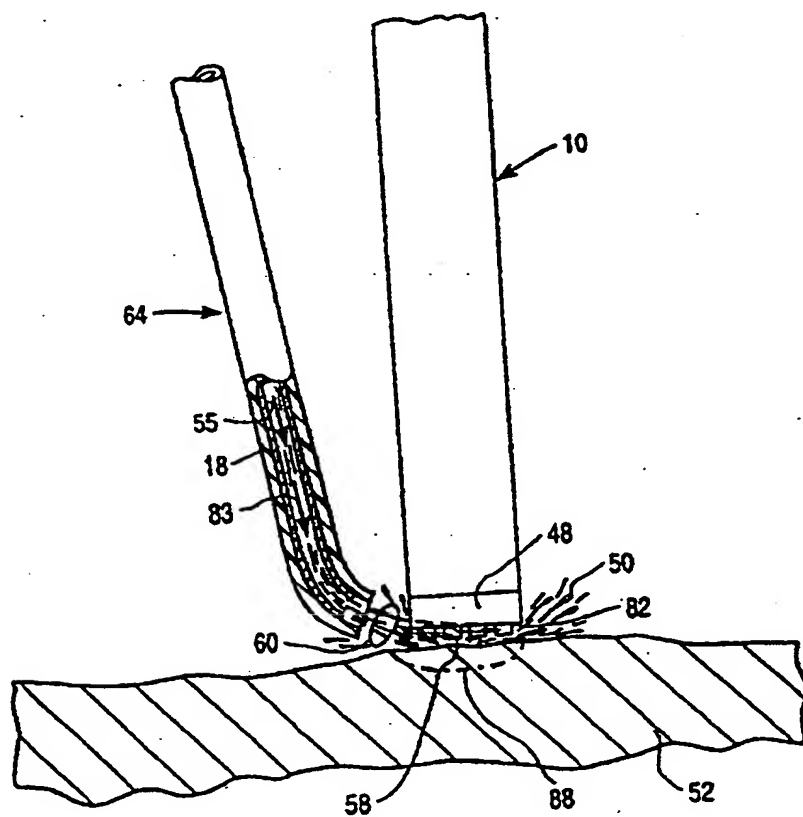


FIG. 7

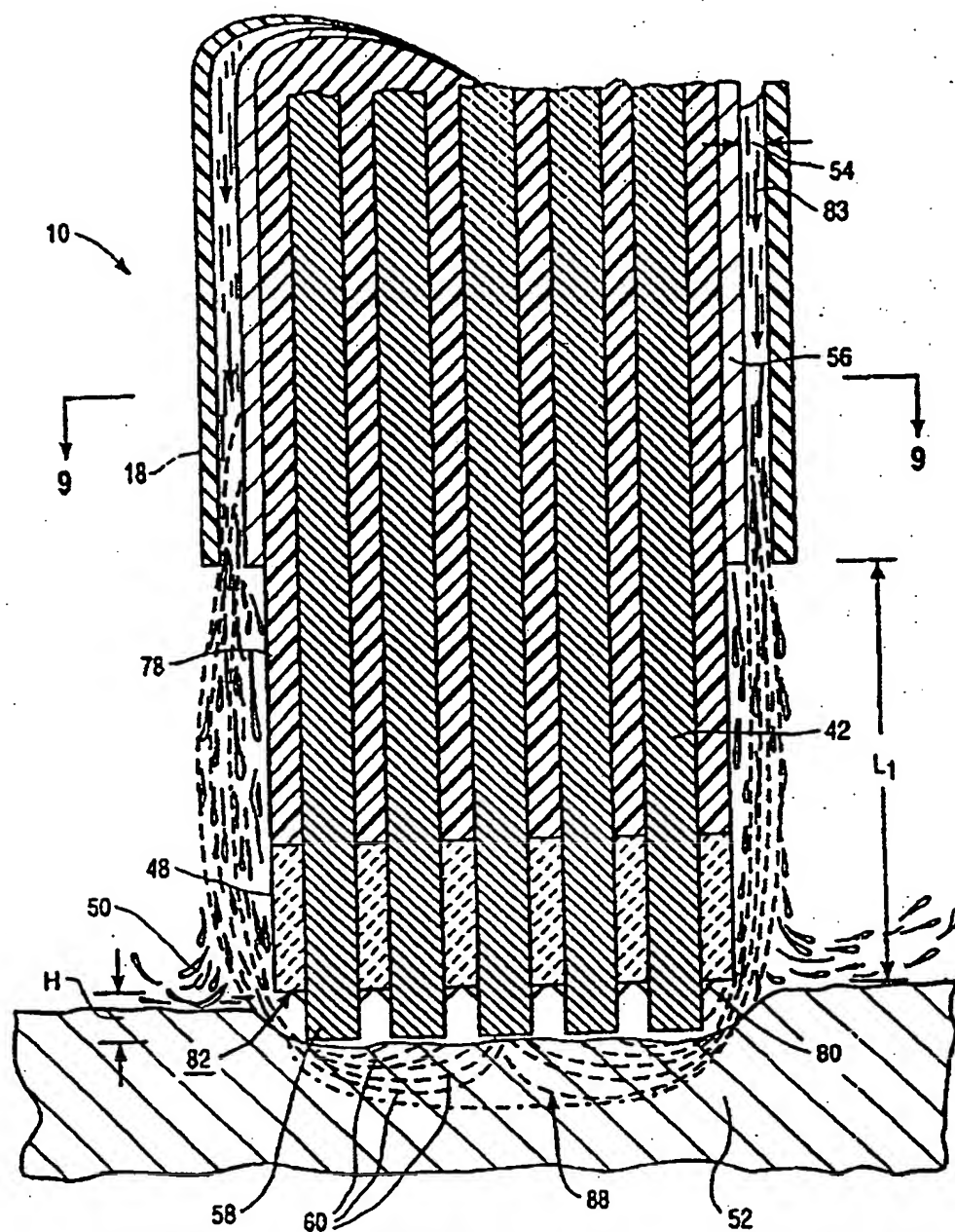


FIG. 8

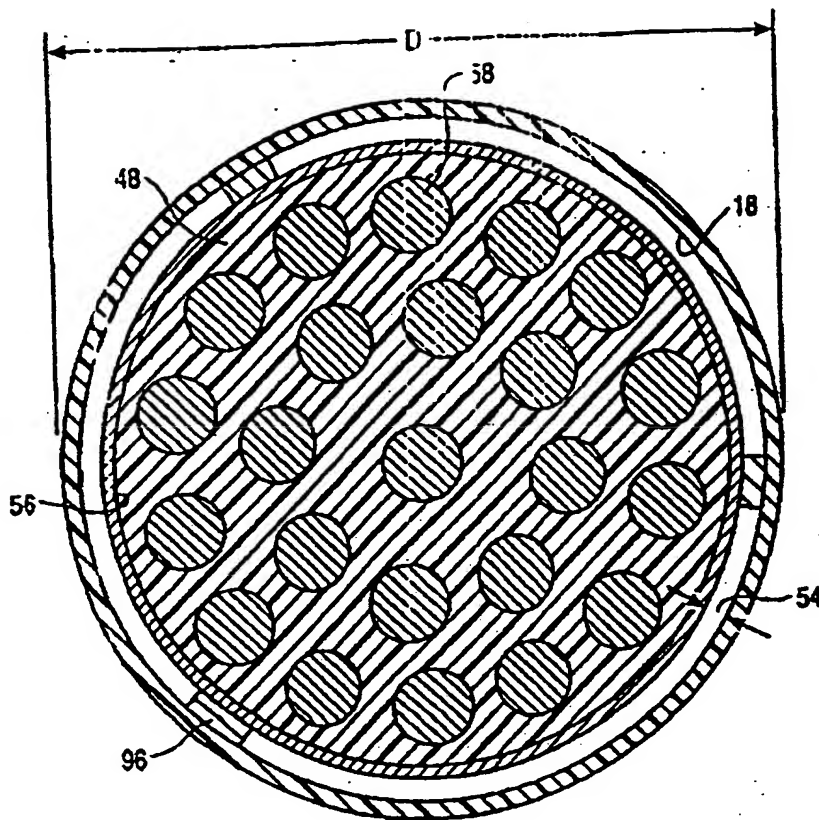


FIG. 9

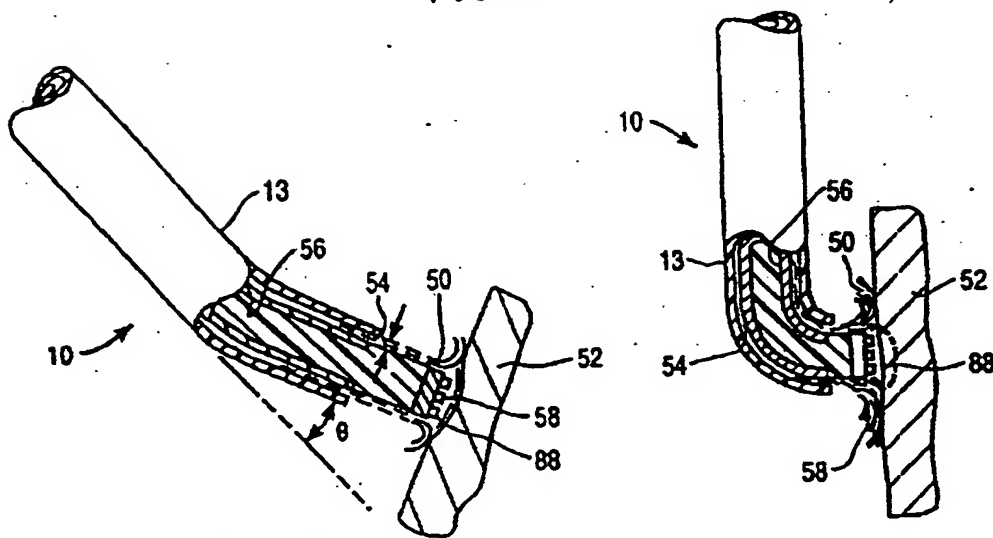


FIG. 10

FIG. 11

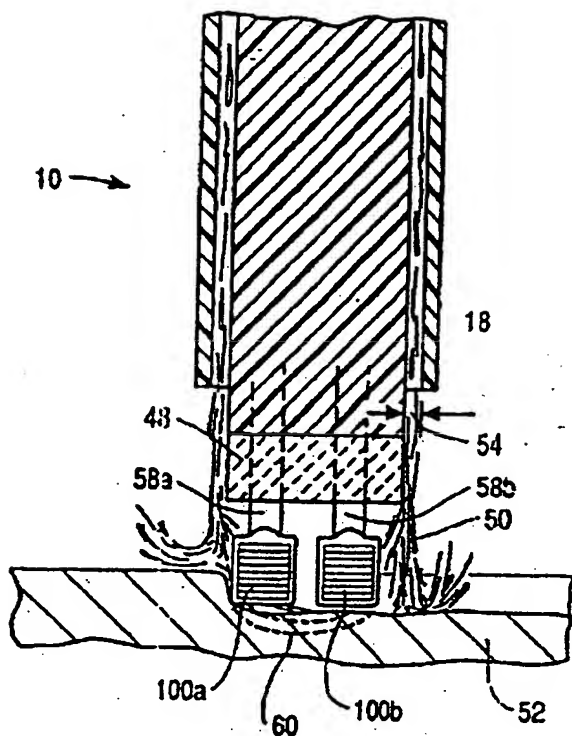


FIG. 12

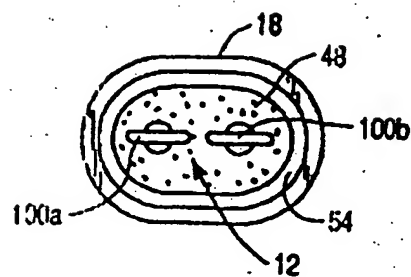


FIG. 13

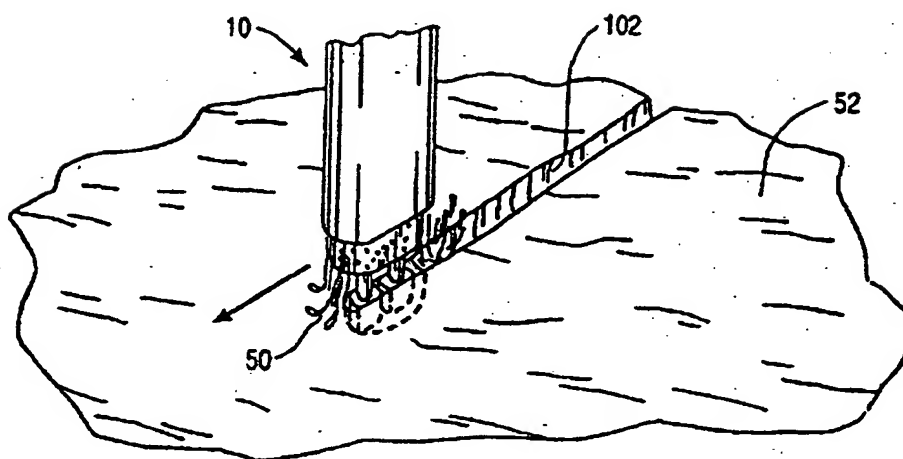


FIG. 14

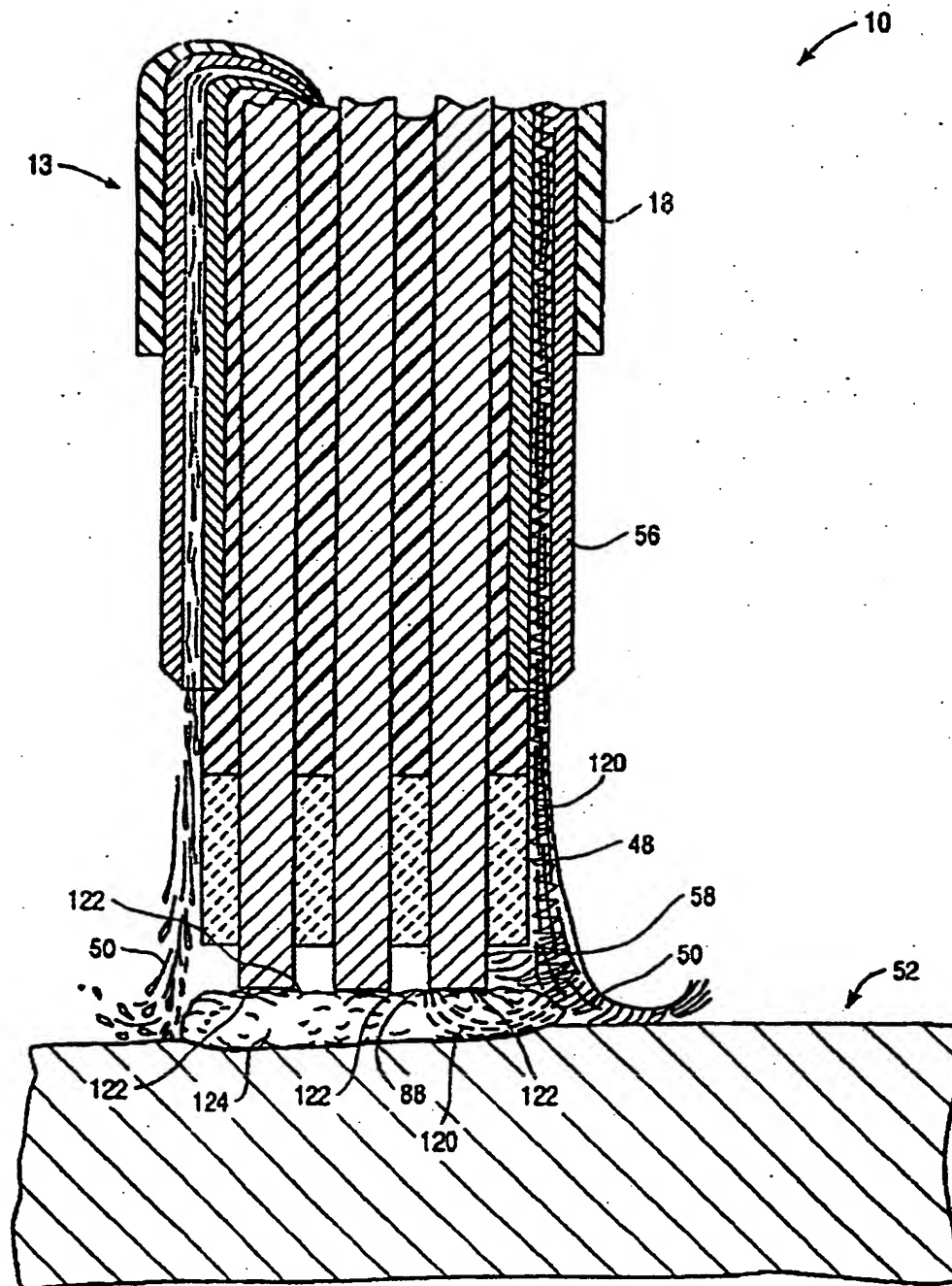


FIG. 15

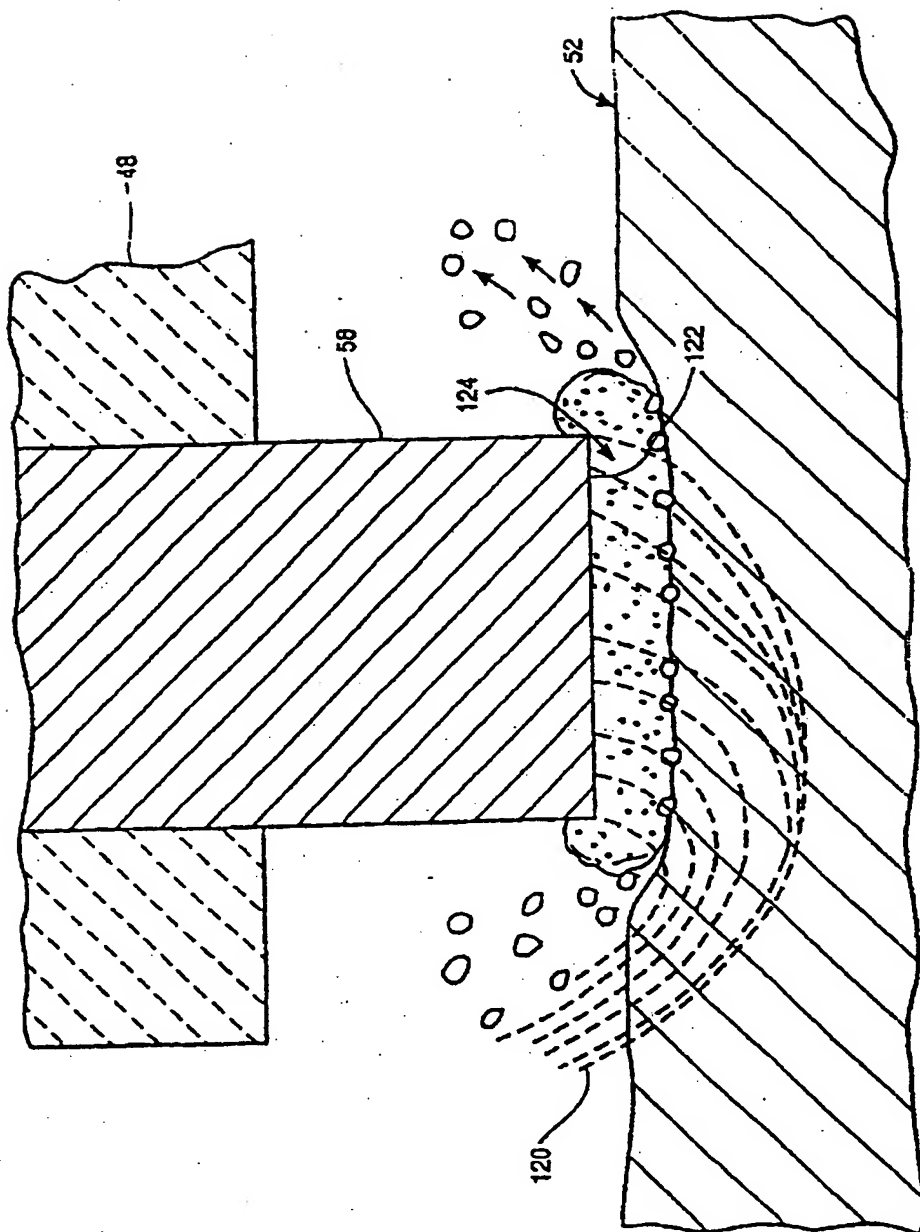


FIG. 16

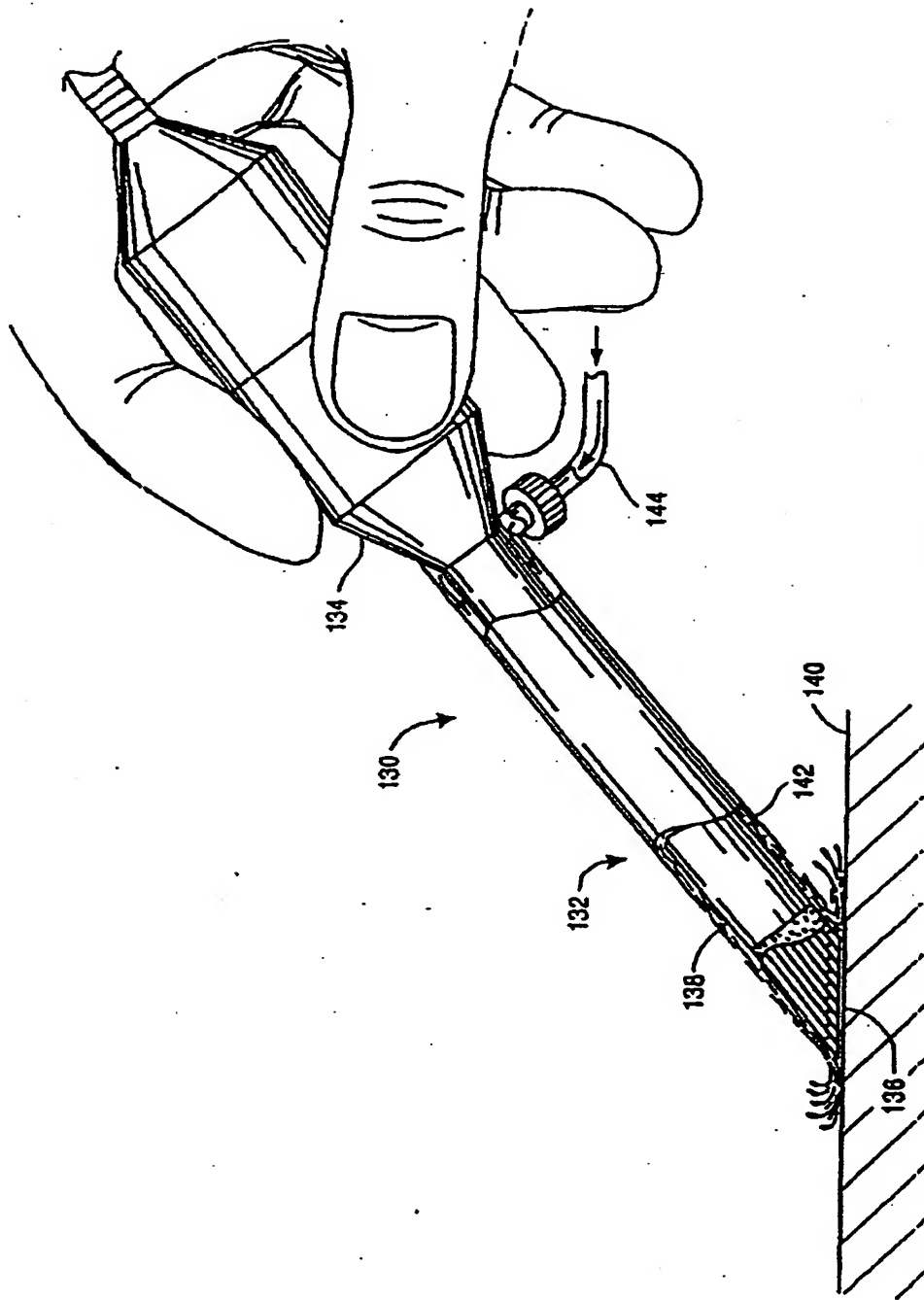


FIG. 17

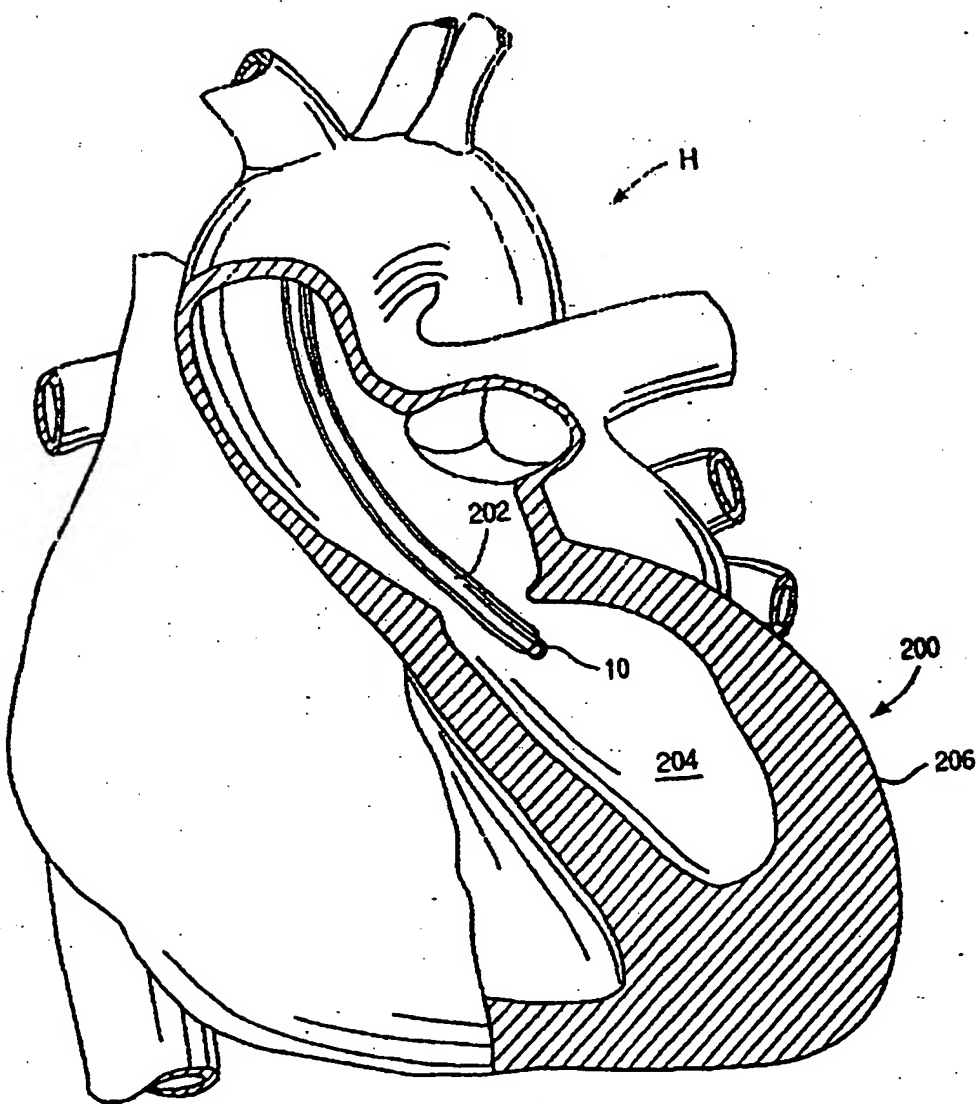


FIG. 18

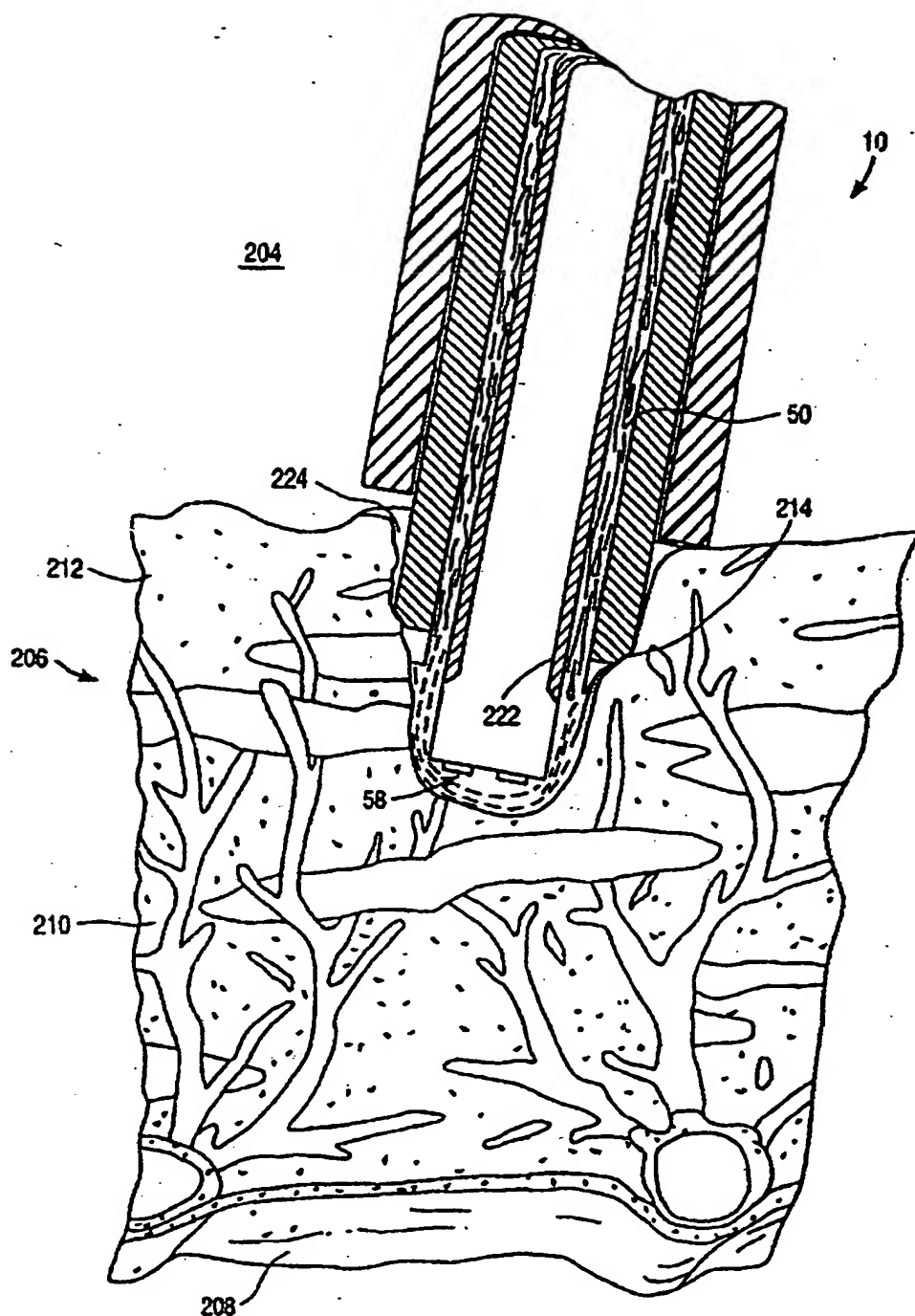


FIG. 19

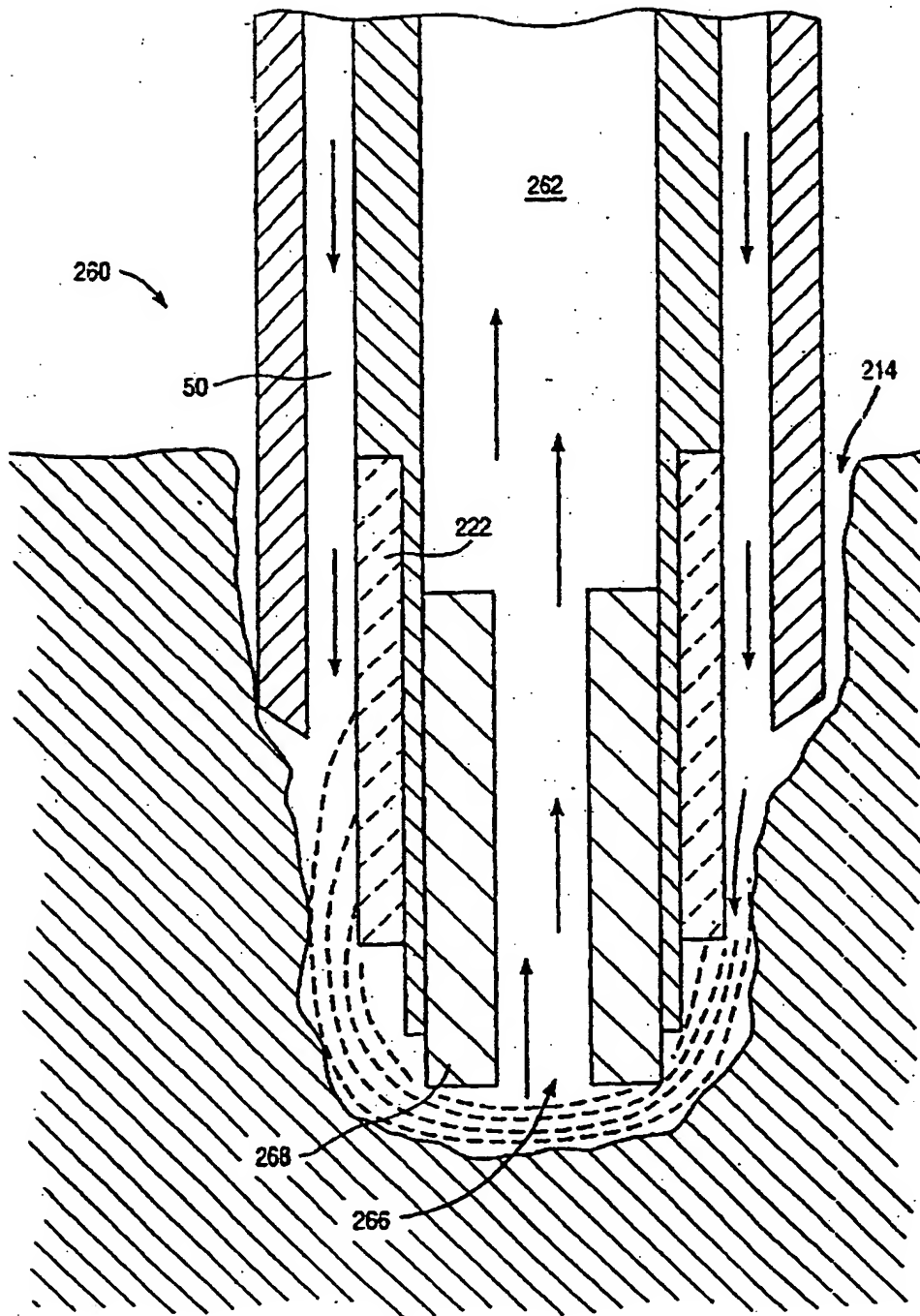


FIG. 20

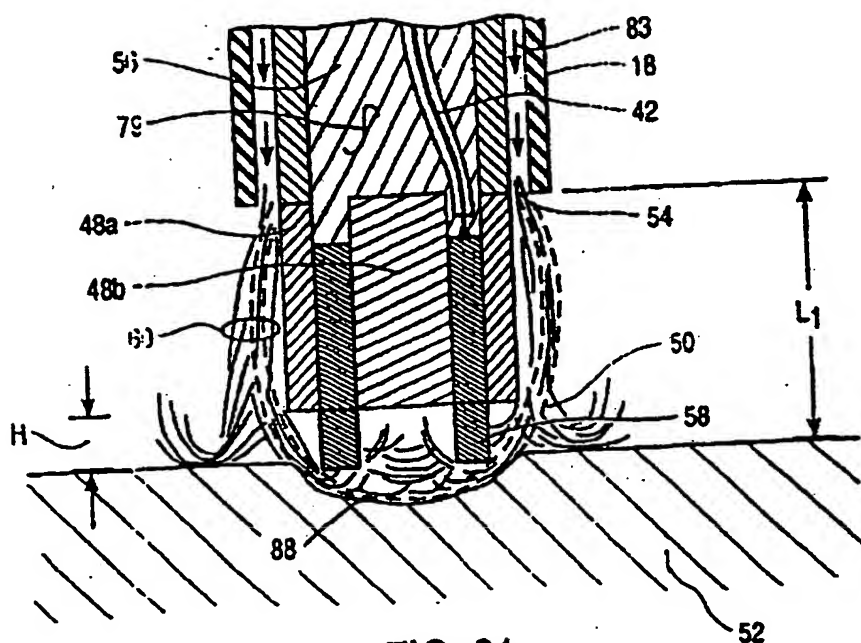


FIG. 21

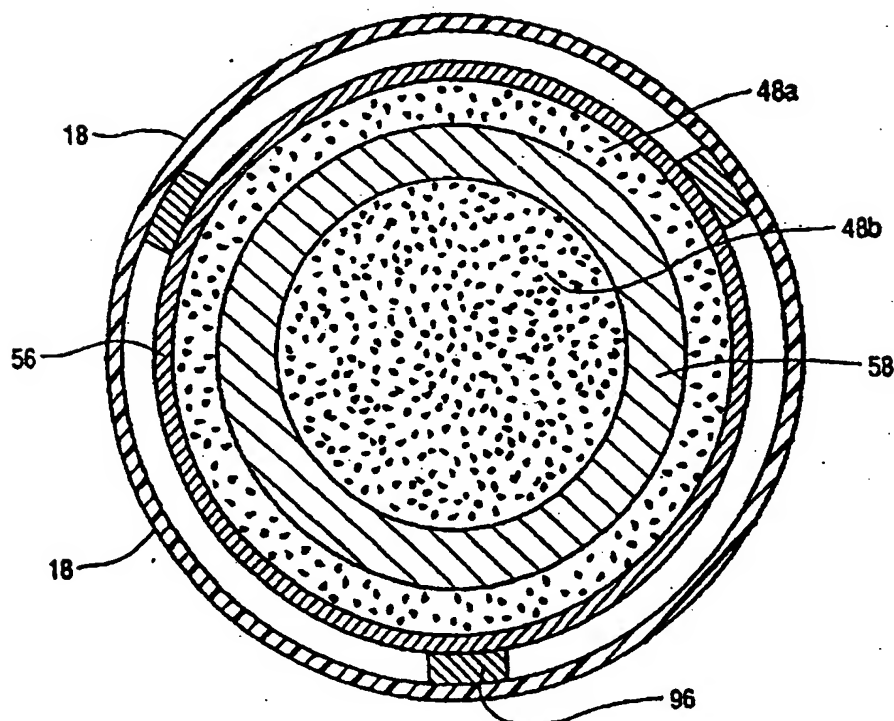


FIG. 22

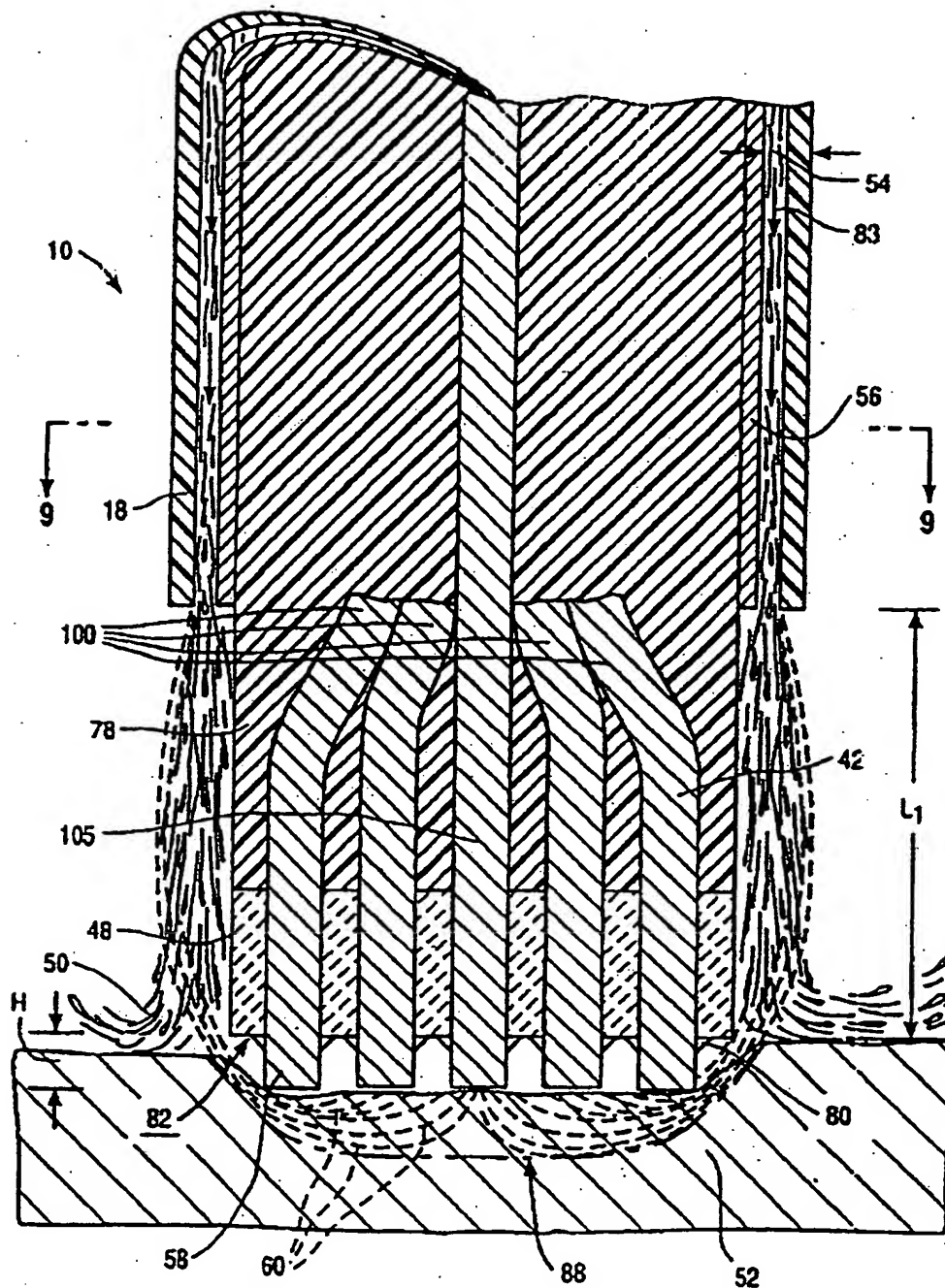


FIG. 23

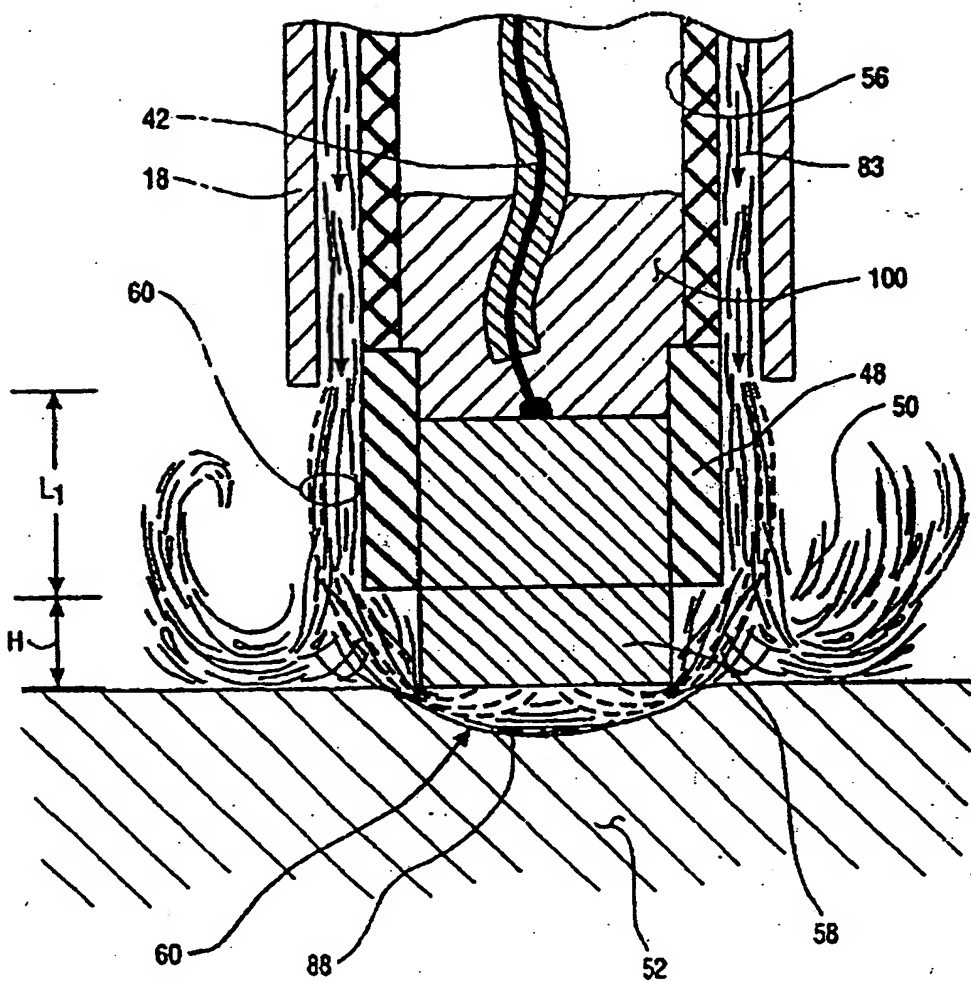


FIG. 24

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

The present invention is a continuation-in-part of application Ser. No. 08/485,219, filed on Jun. 7, 1995 and still pending, which was a continuation-in-part of PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, which was a continuation-in-part of application Ser. No. 08/059,681, filed on May 10, 1993 and now abandoned, which was a continuation-in-part of application Ser. No. 07/958,977, filed on Oct. 9, 1992 now U.S. Pat. No. 5,366,443, which was a continuation-in-part of application Ser. No. 07/817,575, filed on Jan. 7, 1992 now abandoned, the full disclosures of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

Electrosurgical procedures and techniques are particularly advantageous since they generally reduce patient bleeding and trauma associated with cutting operations. Current electrosurgical device and procedures, however, suffer from a number of disadvantages. For example, monopolar devices generally direct electric current along a defined path from the exposed or active electrode through the patient's body to the return electrode, which is externally attached to a suitable location on the patient. This creates the potential danger that the electric current will flow through undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying tissue along and surrounding this pathway.

Bipolar electrosurgical devices have an inherent advantage over monopolar devices because the return current path does not flow through the patient. In bipolar electrosurgical devices, both the active and return electrode are typically exposed so that they may both contact tissue, thereby providing a return current path from the active to the return electrode through the tissue. One drawback with this configuration, however, is that the return electrode may cause tissue desiccation or destruction at its contact point

with the patient's tissue. In addition, the active and return electrodes are typically positioned close together to ensure that the return current flows directly from the active to the return electrode. The close proximity of these electrodes generates the danger that the current will short across the electrodes, possibly impairing the electrical control system and/or damaging or destroying surrounding tissue.

The use of electrosurgical procedures (both monopolar and bipolar) in electrically conductive environments can be further problematic. For example, many arthroscopic procedures require flushing of the region to be treated with isotonic saline (also referred to as normal saline), both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can also cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Many surgical procedures, such as oral, laparoscopic and open surgical procedures, are not performed with the target tissue submerged under an irrigant. In laparoscopic procedures, such as the resection of the gall bladder from the liver, for example, the abdominal cavity is pressurized with carbon dioxide (pneumoperitoneum) to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as the ablation of muscle or gingiva tissue in the mouth, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in a "dry" environment or field (i.e., not submerged under an electrically conducting irrigant).

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated to cause the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as excimer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of fibrocartilage, articular cartilage, and meniscal tissue. The holmium:YAG and Nd:YAG lasers provide much higher volumetric ablation rates, but are much less able to control depth of necrosis than are the slower laser devices. The CO_2 lasers provide high rate of ablation and low depth of tissue necrosis, but cannot operate in a liquid-filled cavity.

For these and other reasons, improved systems and methods are desired for the electrosurgical ablation and cutting of

tissue. These systems and methods should be capable of selectively cutting and ablating tissue and other body structures in electrically conductive environments, such as regions filled with blood or irrigated with electrically conductive solutions, such as isotonic saline, and in relatively dry environments, such as those encountered in oral, dermatological, laparoscopic, thoracoscopic and open surgical procedures. Such apparatus and methods should be able to perform cutting and ablation of tissues, while limiting the depth of necrosis and limiting the damage to tissue adjacent to the treatment site.

DESCRIPTION OF THE BACKGROUND ART

Devices incorporating radio frequency electrodes for use in electrosurgical and electrocautery techniques are described in Rand et al. (1985) *J. Arthro. Surg.* 1:242-246 and U.S. Pat. Nos. 5,281,216; 4,943,290; 4,936,301; 4,593,691; 4,228,800; and 4,202,337. U.S. Pat. Nos. 4,943,290 and 4,036,301 describe methods for injecting non-conducting liquid over the tip of a monopolar electrosurgical electrode to electrically isolate the electrode, while energized, from a surrounding electrically conducting irrigant. U.S. Pat. Nos. 5,195,959 and 4,674,499 describe monopolar and bipolar electrosurgical devices, respectively, that include a conduit for irrigating the surgical site.

U.S. Pat. Nos. 5,217,455, 5,423,803, 5,102,410, 5,282,797, 5,290,273, 5,304,170, 5,312,395, 5,336,217 describe laser treatment methods for removing abnormal skin cells, such as pigmentations, lesions, soft tissue and the like. U.S. Pat. Nos. 5,445,634 and 5,370,642 describe methods for using laser energy to divide, incise or resect tissue during cosmetic surgery. U.S. Pat. No. 5,261,410 is directed to a method and apparatus for detecting and removing malignant tumor tissue. U.S. Pat. Nos. 5,380,316, 4,658,817, 5,389,096, PCT application No. WO 94/14383 and European Patent Application No. 0 515 867 describe methods and apparatus for percutaneous myocardial revascularization. These methods and apparatus involve directing laser energy against the heart tissue to form transverse channels through the myocardium to increase blood flow from the ventricular cavity to the myocardium.

SUMMARY OF THE INVENTION

The present invention provides a system and method for selectively applying electrical energy to structures within or on the surface of a patient's body. The system and method allow the surgical team to perform electrosurgical interventions, such as ablation and cutting of body structures, while limiting the depth of necrosis and limiting damage to tissue adjacent the treatment site. The system and method of the present invention are useful for surgical procedures in relatively dry environments, such as treating and shaping gingiva, for tissue dissection, e.g. separation of gall bladder from the liver, ablation and necrosis of diseased tissue, such as fibroid tumors, and dermatological procedures involving surface tissue ablation on the epidermis, such as scar or tattoo removal, tissue rejuvenation and the like. The present invention may also be useful in electrically conducting environments, such as arthroscopic or cystoscopic surgical procedures. In addition, the present invention is useful for canalizing or boring channels or holes through tissue, such as the ventricular wall of the heart during transmyocardial revascularization procedures.

The method of the present invention comprises positioning an electrosurgical probe adjacent the target tissue so that at least one active electrode is brought into close proximity

to the target site. A return electrode is positioned within an electrically conducting liquid, such as isotonic saline, to generate a current flow path between the target site and the return electrode. High frequency voltage is then applied between the active and return electrode through the current flow path created by the electrically conducting liquid in either a bipolar or monopolar manner. The probe may then be translated, reciprocated or otherwise manipulated to cut the tissue or effect the desired depth of ablation.

The current flow path may be generated by submerging the tissue site in an electrical conducting fluid (e.g., arthroscopic surgery and the like) or by directing an electrically conducting liquid along a fluid path past the return electrode and to the target site to generate the current flow path between the target site and the return electrode. This latter method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, endoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode. The active electrode is preferably disposed at the distal end of the probe and the return electrode is spaced from the active electrode and enclosed within an insulating sheath. This minimizes exposure of the return electrode to surrounding tissue and minimizes possible shorting of the current between the active and return electrodes. In oral procedures, the probe may be introduced directly into the cavity of the open mouth so that the active electrode is positioned against gingival or mucosal tissue. In endoscopic procedures, the probe will typically be passed through a conventional trocar cannula while viewing of the operative site is provided through the use of a laparoscope disposed in a separate cannula.

In a specific aspect of the invention, the high frequency voltage applied between the active and return electrodes generates high voltage gradients in the vicinity of the probe tip. These high voltage gradients are sufficient to create an electric field at the distal boundary of the active electrode(s) that is sufficiently high to break down the tissue through molecular dissociation or disintegration. The high frequency voltage imparts energy to the target site to ablate a thin layer of tissue without causing substantial tissue necrosis beyond the boundary of the thin layer of tissue ablated. This ablative process can be precisely controlled to effect the volumetric removal of tissue as thin as a few layers of cells with minimal heating of or damage to surrounding or underlying tissue structures.

Applicants believe that this precisely controlled ablation is at least partly caused by the high electric field generated around the tip of the active electrode(s) within the electrically conductive liquid. The electric field vaporizes the electrically conductive liquid into a thin layer over at least a portion of the active electrode surface and then ionizes the vapor layer due to the presence of an ionizable species within the liquid. This ionization and the presence of high electric fields in a low density vaporized layer induces the discharge of highly energetic electrons and photons in the form of ultraviolet energy from the vapor layer. The ultraviolet energy and/or energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. This energy discharge can be precisely controlled to effect the volumetric removal of tissue thicknesses ranging from millimeters to a few layers of cells without heating or otherwise damaging surrounding or underlying cell structures.

The active electrode(s) will be spaced away from the target tissue by a suitable distance during the ablation process. This spacing allows for the continual resupply of electrically conducting liquid at the interface between the

active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer or region will remain over at least a portion of the active electrode(s) between the active electrode(s) and the tissue surface. Preferably, the active electrode(s) will be translated and/or rotated transversely relative to the tissue, i.e., in a light brushing motion, to maintain the supply of electrically conducting fluid in the region between the active electrode(s) and the tissue. This dynamic movement of the active electrode(s) over the tissue site also allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize damage to this surrounding tissue.

The apparatus according to the present invention comprises an electrosurgical probe having a shaft with a proximal end, a distal end, and at least one active electrode at or near the distal end. A connector is provided at or near the proximal end of the shaft for electrically coupling the active electrode to a high frequency voltage source. A return electrode coupled to the voltage source is spaced a sufficient distance from the active electrode to substantially avoid or minimize current shorting therebetween and, in dry environments, to shield the return electrode from tissue at the target site of ablation or from the surgeon. In irrigant flooded environments, such as arthroscopic surgery, the area of the return electrode is sufficiently large to result in low current densities that effectively preclude damage to nearby tissue. The return electrode may be provided integral with the shaft of the probe or it may be separate from the shaft (e.g., on a liquid supply instrument). In both cases, the return electrode defines an inner, annular surface of the pathway for flow of electrically conducting liquid therethrough. The liquid is directed past the surface of the return electrode and over the active electrode to thereby provide a return current flow path between the target tissue site and the return electrode.

The active and return electrodes will preferably be configured such that, upon the application of a sufficient high-frequency voltage, a thin layer of the electrically conducting liquid is vaporized over at least a portion of the active electrode(s) in the region between the active electrode(s) and the target tissue. To accomplish this, the active electrode(s) will be configured such that high electric field densities form at the distal tips of the active electrode(s). By way of example, the present invention may utilize an electrode array of electrode terminals flush with or recessed from or extending from the distal end of the probe. The electrode terminals will preferably have a sufficiently small area, extension (or recession) length from the probe and sharp edges and/or surface asperities such that localized high current densities are promoted on the electrode terminals which, in turn, lead to the formation of a vaporized layer or region over at least a portion of the active electrode(s) followed by the high electric field induced breakdown (i.e., ionization) of ionizable species within the vapor layer or region and the emission of photon and/or electrons of sufficient energy to cause dissociation of molecules within the target tissue.

In an exemplary embodiment, the active electrode(s) are sized and arranged to create localized sources of energy (e.g., point sources or sources with a relatively small effective radius) at the distal tips of the electrode(s) when a sufficiently high frequency voltage is applied to the return and active electrodes. These small localized sources generate intense energy at the distal ends of the electrodes for molecular dissociation or ablation of tissue in contact with or in close proximity to the electrode tips. In addition, since the localized sources have relatively small radii, the energy

flux decreases with the square of the distance from the localized sources so that the tissue at greater distances from the electrode tips are not significantly affected by the energy flux.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the electrosurgical system including an electrosurgical probe, an electrically conducting liquid supply and an electrosurgical power supply constructed in accordance with the principles of the present invention;

FIG. 2A is an enlarged, cross-sectional view of the distal tip of the electrosurgical probe of FIG. 1 illustrating an electrode arrangement suitable for rapid cutting and ablation of tissue structures;

FIG. 2B is an enlarged end view of the distal tip of the electrosurgical probe of FIG. 1;

FIG. 2C is a cross-sectional view of the proximal end of the electrosurgical probe, illustrating an arrangement for coupling the probe to the electrically conducting liquid supply of FIG. 1;

FIG. 3 is a detailed cross-sectional view of an alternative embodiment of the electrosurgical probe of FIG. 1;

FIG. 4 is an end view of the distal end of the electrosurgical probe of FIG. 3;

FIG. 5 is an end view of another embodiment of the electrosurgical probe of FIG. 1;

FIG. 6 is a partial cross-sectional side view of a further embodiment of the electrosurgical probe with the electrode array disposed transversely to the axis of the probe;

FIG. 7 is a partial front cross-sectional view of an electrosurgical probe and an electrically conductive liquid supply shaft illustrating use of the probe and the shaft in ablating target tissue;

FIG. 8 is an enlarged, cross-sectional view of the distal tip of yet another embodiment of the electrosurgical probe of FIG. 1;

FIG. 9 is a detailed end view of the probe of FIG. 8;

FIG. 10 is a side view of an electrosurgical probe having a shaft with an angled distal portion;

FIG. 11 is a side view of an electrosurgical probe having a shaft with a perpendicular distal portion;

FIG. 12 is a schematic view of an electrosurgical probe having two screwdriver-shaped electrodes extending from the distal end;

FIG. 13 is an end view of the probe of FIG. 12;

FIG. 14 illustrates use of the probe of FIG. 12 for the rapid cutting of tissue;

FIG. 15 is a cross-sectional view of the distal tip of the electrosurgical probe, illustrating electric field lines between the active and return electrodes;

FIG. 16 is an enlarged cross-sectional view of the distal tip of the probe of FIG. 15, illustrating a vapor layer formed between the active electrodes and the target tissue;

FIG. 17 is a cross-sectional view of an alternative electrosurgical probe for applying high frequency voltage to epidermal tissue layers;

FIG. 18 is a sectional view of the human heart, illustrating the electrosurgical probe within the ventricular cavity for performing a transmyocardial revascularization procedure;

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FIG. 19 is a cross-sectional view of the probe boring a channel through the ventricular wall;

FIG. 20 depicts an alternative embodiment of the probe of FIG. 19 having an inner lumen for aspirating fluid and gases from the transmural channel;

FIG. 21 depicts a distal portion of an alternative embodiment of the probe of FIGS. 2A-2C incorporating a single electrode with a tubular geometry;

FIG. 22 is a cross-sectional view of the distal end of the probe of FIG. 21;

FIG. 23 is a side cross-sectional view of a distal portion of a further embodiment of the probe of FIGS. 2A-2C incorporating a multiplicity of electrodes which converge to a single electrode lead; and

FIG. 24 is a side cross-sectional view of a distal portion of yet another embodiment of the probe of FIGS. 2A-2C incorporating a single electrode connected to a single electrode lead.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a system and method for selectively applying electrical energy to a target location within or on a patient's body, such as solid tissue or the like, particularly including gingival tissues and mucosal tissues located in the mouth or epidermal tissue on the outer skin. In addition, tissues which may be treated by the system and method of the present invention include tumors, abnormal tissues, and the like. The invention may also be used for canalizing or boring channels or holes through tissue, such as the ventricular wall during transmural revascularization procedures. For convenience, the remaining disclosure will be directed specifically to the cutting, shaping or ablation of gingival or mucosal tissue in oral surgical procedures, the surface tissue ablation of the epidermis in dermatological procedures and the canalization of channels through the myocardium of the heart, but it will be appreciated that the system and method can be applied equally well to procedures involving other tissues of the body, as well as to other procedures including open surgery, laparoscopic surgery, thoracoscopic surgery, and other endoscopic surgical procedures.

In addition, the present invention is particularly useful in procedures where the tissue site is flooded or submerged with an electrically conducting fluid, such as isotonic saline. Such procedures, e.g., arthroscopic surgery and the like, are described in detail in co-pending PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, the complete disclosure of which has been incorporated herein by reference.

The present invention may use a single active electrode or an electrode array distributed over a distal contact surface of a probe. The electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive liquids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the probe to form a single wire that couples to a power source.

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The electrosurgical probe will comprise a shaft having a proximal end and a distal end which supports an active electrode. The shaft may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. Usually, the shaft will be a narrow-diameter rod or tube, more usually having dimensions which permit it to be introduced into a body cavity, such as the mouth or the abdominal cavity, through an associated trocar or cannula in a minimally invasive procedure, such as arthroscopic, laparoscopic, thoracoscopic, and other endoscopic procedures. Thus, the shaft will typically have a length of at least 5 cm for oral procedures and at least 10 cm, more typically being 20 cm, or longer for endoscopic procedures. The shaft will typically have a diameter of at least 1 mm and frequently in the range from 1 to 10 mm. Of course, for dermatological procedures on the outer skin, the shaft may have any suitable length and diameter that would facilitate handling by the surgeon.

The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The circumscribed area of the electrode array is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm², and will usually include at least two isolated electrode terminals, more usually at least four electrode terminals, preferably at least six electrode terminals, and often 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. By bringing the electrode array(s) on the contact surface(s) in close proximity with the target tissue and applying high frequency voltage between the array(s) and an additional common or return electrode in direct or indirect contact with the patient's body, the target tissue is selectively ablated or cut, permitting selective removal of portions of the target tissue while desirably minimizing the depth of necrosis to surrounding tissue. In particular, this invention provides a method and apparatus for effectively ablating and cutting tissue which may be located in close proximity to other critical organs, vessels or structures (e.g., teeth, bone) by simultaneously (1) causing electrically conducting liquid to flow between the common and active electrodes, (2) applying electrical energy to the target tissue surrounding and immediately adjacent to the tip of the probe, (3) bringing the active electrode(s) in close proximity with the target tissue using the probe itself, and (4) optionally moving the electrode array axially and/or transversely over the tissue.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said probe and is connected to a power source which is isolated from each of the other electrodes in the array or to circuitry which limits or interrupts current flow to the electrode when low resistivity material (e.g., blood or electrically conductive saline irrigant) causes a lower impedance path between the common electrode and the individual electrode terminal. The isolated power sources for each individual electrode may be separate power supply circuits having internal impedance

characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered, may be a single power source which is connected to each of the electrodes through independently actuatable switches or may be provided by independent current limiting elements, such as inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the probe, connectors, cable, controller or along the conductive path from the controller to the distal tip. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode(s) due to oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the probe may be composed of many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the target tissue is achieved by connecting each individual electrode terminal and the common electrode to a power source having independently controlled or current limited channels. The common electrode may be a tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting liquid between the active and common electrodes. The application of high frequency voltage between the common electrode and the electrode array results in the generation of high electric field intensities at the distal tips of the electrodes with conduction of high frequency current from each individual electrode terminal to the common electrode. The current flow from each individual electrode terminal to the common electrode is controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the target tissue while minimizing energy delivery to surrounding (non-target) tissue and any conductive fluids which may be present (e.g., blood, electrolytic irrigants such as saline, and the like).

In a preferred aspect, this invention takes advantage of the differences in electrical resistivity between the target tissue (e.g., gingiva, muscle, fascia, tumor, epidermal, heart or other tissue) and the surrounding conductive liquid (e.g., isotonic saline irrigant). By way of example, for any selected level of applied voltage, if the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is isotonic saline irrigant liquid (having a relatively low electrical impedance), the current control means connected to the individual electrode will limit current flow so that the heating of intervening conductive liquid is minimized. On the other hand, if a portion of or all of the electrical conduction path between the common electrode and one of the individual electrode terminals within the electrode array is gingival tissue (having a relatively higher electrical impedance), the current control circuitry or switch connected to the individual electrode will allow current flow sufficient for the deposition of electrical energy and associated ablation or electrical breakdown of the target tissue in the immediate vicinity of the electrode surface.

The application of a high frequency voltage between the common or return electrode and the electrode array for appropriate time intervals effects ablation, cutting or reshaping of the target tissue. The tissue volume over which energy is dissipated (i.e., a high voltage gradient exists) may be precisely controlled, for example, by the use of a multiplicity of small electrodes whose effective diameters range from about 2 mm to 0.01 mm, preferably from about 1 mm to 0.05 mm, and more preferably from about 0.5 mm to 0.1 mm. Electrode areas for both circular and non-circular terminals

will have a contact area (per electrode) below 5 mm², preferably being in the range from 0.0001 mm² to 1 mm², and more preferably from 0.005 mm² to 0.5 mm². The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue necrosis as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal. Energy deposition in tissue sufficient for irreversible damage (i.e., necrosis) has been found to be limited to a distance of about one-half to one electrode diameter. This is a particular advantage over prior electro-surgical probes employing single and/or larger electrodes where the depth of tissue necrosis may not be sufficiently limited.

In previous electrosurgical devices, increased power application and ablation rates have been achieved by increasing the electrode area. Surprisingly, with the present invention, it has been found that the total electrode area can be increased (to increase power delivery and ablation rate) without increasing the depth of necrosis by providing multiple small electrode terminals. Preferably, the terminals will be spaced apart by a distance in the range from about one-half diameter to one diameter for optimum power delivery, as discussed below. The depth of necrosis may be further controlled by switching the applied voltage off and on to produce pulses of current, the pulses being of sufficient duration and associated energy density to effect ablation and/or cutting while being turned off for periods sufficiently long to allow for thermal relaxation between energy pulses. In this manner, the energy pulse duration and magnitude and the time interval between energy pulses are selected to achieve efficient rates of tissue ablation or cutting while allowing the temperature of the treated zone of tissue to "relax" or return to normal physiologic temperatures (usually to within 10° C. of normal body temperature [37° C.], preferably to within 5° C.) before the onset of the next energy (current) pulse.

In addition to the above described methods, the applicant has discovered another mechanism for ablating tissue while minimizing the depth of necrosis. This mechanism involves applying a high frequency voltage between the active electrode surface and the return electrode to develop high electric field intensities in the vicinity of the target tissue site. The high electric field intensities lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). In other words, the tissue structure is volumetrically removed through molecular disintegration of complex organic molecules into non-viable atoms and molecules, such as hydrogen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to transforming the tissue material from a solid form directly to a vapor form, as is typically the case with ablation.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize the electrically conducting liquid over at least a portion of the active electrode(s) in the region between the distal tip of the active electrode and the target tissue. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the voltage differential between the active electrode tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under optimal conditions, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target

tissue. This energy may be in the form of energetic photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons) or a combination thereof.

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Based on initial experiments, applicants believe that the ionization of atoms within the vapor layer produced in isotonic saline (containing sodium chloride) leads to the generation of energetic photons having wavelengths, by way of example, in the range of 306 to 315 nanometers (ultraviolet spectrum) and 588 to 590 nanometers (visible spectrum). In addition, the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The photon energy produces photoablation through photochemical and/or photothermal processes to disintegrate tissue thicknesses as small as several cell layers of tissue at the target site. This photoablation is a "cold" ablation, which means that the photon energy transfers very little heat to tissue beyond the boundaries of the region of tissue ablated. The cold ablation provided by photon energy can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells. The depth of necrosis will be typically be about 0 to 400 microns and usually 10 to 200 microns. Applicants believe that the "fragments" of disintegrated tissue molecules carry away much of the energy which is deposited on the surface of the target tissue, thereby allowing molecular disintegration of tissue to occur while limiting the amount of heat transfer to the surrounding tissue.

In addition, other competing mechanisms may be contributing to the ablation of tissue. For example, tissue destruction or ablation may also be caused by dielectric breakdown of the tissue structural elements or cell membranes from the highly concentrated intense electric fields at the tip portions of the electrode(s). According to the teachings of the present invention, the active electrode(s) are sized and have exposed surfaces areas which, under proper conditions of applied voltage, cause the formation of a vaporized region or layer over at least a portion of the surface of the active electrode(s). This layer or region of vaporized electrically conducting liquid creates the conditions necessary for ionization within the vaporized region or layer and the generation of energetic electrons and photons. In addition, this layer or region of vaporized electrically conducting liquid provides a high electrical impedance between the electrode and the adjacent tissue so that only low levels of current flow across the vaporized layer or region into the tissue, thereby minimizing joulean heating in, and associated necrosis of, the tissue.

As discussed above, applicants have found that the density of the electrically conducting liquid at the distal tips of the active electrodes should be less than a critical value to form a suitable vapor layer. For aqueous solutions, such as water or isotonic saline, this upper density limit is approximately 10^{20} atoms/cm³, which corresponds to about 3×10^{-3} grams/cm³. Applicants also believe that once the density in the vapor layer reaches a critical value (e.g., approximately 10^{20} atoms/cm³ for aqueous solutions), electron avalanche occurs. The growth of this avalanche is retarded when the space charge generated fields are on the order of the external field. Spatial extent of this region should be larger than the distance required for an electron avalanche to become critical and for an ionization front to develop. This ionization front develops and propagates across the vapor layer via a sequence of processes occurring in the region ahead of the front, viz, heat by electron injection, lowering of the local liquid density below the critical value and avalanche growth of the charged particle concentration.

Electrons accelerated in the electric field within the vapor layer will apparently become trapped after one or a few scatterings. These injected electrons serve to create or sustain a low density region with a large mean free path to enable subsequently injected electrons to cause impact ionization within these regions of low density. The energy evolved at each recombination is on the order of half of the energy band gap (i.e., 4 to 5 eV). It appears that this energy can be transferred to another electron to generate a highly energetic electron. This second, highly energetic electron may have sufficient energy to bombard a molecule to break its bonds, i.e., dissociate the molecule into free radicals.

The electrically conducting liquid should have a threshold conductivity in order to suitably ionize the vapor layer for the inducement of energetic electrons and photons. The electrical conductivity of the fluid (in units of milliSiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. The electrical conductivity of the channel trailing the ionization front should be sufficiently high to maintain the energy flow required to heat the liquid at the ionization front and maintain its density below the critical level. In addition, when the electrical conductivity of the liquid is sufficiently high, ionic pre-breakdown current levels (i.e., current levels prior to the initiation of ionization within the vapor layer) are sufficient to also promote the initial growth of bubbles within the electrically conducting liquid (i.e., regions whose density is less than the critical density).

Asperities on the surface of the active electrode(s) appear to promote localized high current densities which, in turn, promote bubble nucleation at the site of the asperities whose enclosed density (i.e., vapor density) is below the critical density to initiate ionization breakdown within the bubble. Hence, a specific configuration of the present invention creates regions of high current densities on the tips of the electrode(s) (i.e., the surface of the electrode(s) which are to engage and ablate or cut tissue). Regions of high current densities can be achieved via a variety of methods, such as producing sharp edges and corners on the distal tips of the electrodes or vapor blasting, chemically etching or mechanically abrading the distal end faces of the active electrodes to produce surface asperities thereon. Alternatively, the electrode terminals may be specifically designed to increase the edge/surface area ratio of the electrode terminals. For example, the electrode terminal(s) may be hollow tubes

having a distal, circumferential edge surrounding an opening. The terminals may be formed in an array as described above or in a series of concentric terminals on the distal end of the probe. High current densities will be generated around the circumferential edges of the electrode terminals to promote nucleate bubble formation.

The voltage applied between the common electrode and the electrode array will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, and preferably being between about 50 kHz and 400 kHz. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 50 volts to 800 volts, and more preferably being in the range from about 100 volts to 400 volts. These frequencies and voltages will result in peak-to-peak voltages and currents that are sufficient to vaporize the electrically conductive liquid and, in turn, create the conditions within the vaporized region which result in high electric fields and emission of energetic photons and/or electrons to ablate tissue. Typically, the peak-to-peak voltage will be in the range of 200 to 2000 volts and preferably in the range of 300 to 1400 volts and more preferably in the range of 700 to 900 volts.

As discussed above, the voltage is usually delivered in a series of voltage pulses with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the pulsed duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about 50% for the present invention, as compared with lasers which typically have a duty cycle of about 0.0001%.

Applicants believe that the present invention is capable of obtaining high ablation rates with effectively continuous mode operation and high duty cycles because the source of energy emitted from the edges and tips of the small electrode terminals is effectively a point source or a source having a relatively small effective radius. As is well known in the art, the flux emitted from a point source and crossing a boundary in spherical space generally decreases as the square of distance from the source. Thus, the "energy source" of the present invention (i.e., the intense electric field, the energetic photons or the energetic electrons) is highly concentrated by virtue of the geometry of the emitting electrodes and the source of energy at the tips of the electrodes. As a result, only those regions or areas that are very close to the electrode tips or source will be exposed to high energy fluxes. Consequently, ablation will typically only occur in tissue layers effectively in contact or in very close proximity with the tips of the electrodes. The tissue at greater distances from the electrode tips are not significantly affected since the energy flux is too low at these distances to irreversibly affect or damage tissue.

Usually, the current level will be selectively limited or controlled and the voltage applied will be independently adjustable, frequently in response to the resistance of tissues and/or fluids in the pathway between an individual electrode and the common electrode. Also, the applied current level may be in response to a temperature control means which maintains the target tissue temperature with desired limits at the interface between the electrode arrays and the target tissue. The desired tissue temperature along a propagating surface just beyond the region of ablation will usually be in the range from about 40° C. to 100° C., and more usually from about 50° C. to 60° C. The tissue being ablated (and

hence removed from the operation site) immediately adjacent the electrode array may reach even higher temperatures.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from tens of milliwatts to tens of watts per electrode, depending on the target tissue being ablated, the rate of ablation desired or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the current level according to the specific requirements of a particular oral surgery, dermatological procedure, open surgery or other endoscopic surgery procedure.

The power source may be current limited or otherwise controlled so that undesired heating of electrically conductive fluids or other low electrical resistance media does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10 μ H to 50,000 μ H, depending on the electrical properties of the target tissue, the desired ablation rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode in contact with a low resistance medium (e.g., saline irrigant), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode into the low resistance medium (e.g., saline irrigant).

As an alternative to such passive circuit structures, regulated current flow to each electrode terminal may be provided by a multi-channel power supply. A substantially constant current level for each individual electrode terminal within a range which will limit power delivery through a low resistance path, e.g., isotonic saline irrigant, and would be selected by the user to achieve the desired rate of cutting or ablation. Such a multi-channel power supply thus provides a substantially constant current source with selectable current level in series with each electrode terminal, wherein all electrodes will operate at or below the same, user selectable maximum current level. Current flow to all electrode terminals could be periodically sensed and stopped if the temperature measured at the surface of the electrode array exceeds user selected limits. Particular control system designs for implementing this strategy are well within the skill of the art.

Yet another alternative involves the use of one or several power supplies which allow one or several electrodes to be simultaneously energized and which include active control means for limiting current levels below a preselected maximum level. In this arrangement, only one or several electrodes would be simultaneously energized for a brief period. Switching means would allow the next one or several electrodes to be energized for a brief period. By sequentially energizing one or several electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time). As before, a resistance measurement means may be employed for each electrode prior to the application of power wherein a (measured) low resistance (below some preselected level) will prevent that electrode

from being energized during a given cycle. By way of example, the sequential powering and control scheme of the present invention would function in a manner similar to an automobile distributor. In this example, an electrical contact rotates past terminals connected to each spark plug. In this example, each spark plug corresponds to the exposed surface of each of the electrodes. In addition, the present invention includes the means to measure the resistance of the medium in contact with each electrode and cause voltage to be applied only if the resistance exceeds a preselected level.

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For example, the array of active electrode terminals may be connected to a single lead that extends through the probe shaft to a power source of high frequency current. Alternatively, the probe may incorporate a single electrode that extends directly through the probe shaft or is connected to a single lead that extends to the power source.

The active electrode(s) are formed over a contact surface on the shaft of the electrosurgical probe. The common (return) electrode surface will be recessed relative to the distal end of the probe and may be recessed within the conduit provided for the introduction of electrically conducting liquid to the site of the target tissue and active electrode(s). In the exemplary embodiment, the shaft will be cylindrical over most of its length, with the contact surface being formed at the distal end of the shaft. In the case of endoscopic applications, the contact surface may be recessed since it helps protect and shield the electrode terminals on the surface while they are being introduced, particularly while being introduced through the working channel of a trocar channel or a viewing scope.

The area of the contact surface can vary widely, and the contact surface can assume a variety of geometries, with particular areas in geometries being selected for specific applications. Active electrode contact surfaces can have areas in the range from 0.25 mm² to 50 mm², usually being from 1 mm² to 20 mm². The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) will be formed at the distal tip of the electrosurgical probe shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical probe shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in electrosurgical procedures.

During the surgical procedure, the distal end of the probe or the active electrode(s) will be maintained at a small distance away from the target tissue surface. This small spacing allows for the continual resupply of electrically conducting liquid into the interface between the active electrode(s) and the target tissue surface. This continual resupply of the electrically conducting liquid helps to ensure that the thin vapor layer will remain between active electrode(s) and the tissue surface. In addition, dynamic movement of the active electrode(s) over the tissue site allows the electrically conducting liquid to cool the tissue surrounding recently ablated areas to minimize thermal damage to this surrounding tissue. Typically, the active electrode(s) will be about 0.02 to 2 mm from the target tissue and preferably about 0.05 to 0.5 mm during the ablation process. One method of maintaining this space is to translate and/or rotate the probe transversely relative to the tissue, i.e.,

a light brushing motion, to maintain a thin vaporized layer or region between the active electrode and the tissue. Of course, if coagulation of a deeper region of tissue is necessary (e.g., for sealing a bleeding vessel imbedded within the tissue), it may be desirable to press the active electrode against the tissue to effect joulean heating thereof.

Referring to the drawings in detail, wherein like numerals indicate like elements, an electrosurgical system 11 is shown constructed according to the principles of the present invention. Electrosurgical system 11 generally comprises an electrosurgical probe 10 connected to a power supply 28 for providing high frequency voltage to a target tissue 52 and a liquid source 21 for supplying electrically conducting fluid 50 to probe 10.

In an exemplary embodiment as shown in FIG. 1, electrosurgical probe 10 includes an elongated shaft 13 which may be flexible or rigid, with flexible shafts optionally including support cannulas or other structures (not shown). Probe 10 includes a connector 19 at its proximal end and an array 12 of electrode terminals 58 disposed on the distal tip of shaft 13. A connecting cable 34 has a handle 22 with a connector 20 which can be removably connected to connector 19 of probe 10. The proximal portion of cable 34 has a connector 26 to couple probe 10 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors 42 (see FIG. 2C). Power supply 28 has a selection means 30 to change the applied voltage level. Power supply 28 also includes means for energizing the electrodes 58 of probe 10 through the depression of a pedal 39 in a foot pedal 37 positioned close to the user. The foot pedal 37 may also include a second pedal (not shown) for remotely adjusting the energy level applied to electrodes 58. The specific design of a power supply which may be used with the electrosurgical probe of the present invention is described in parent application PCT US 94/051168, the full disclosure of which has previously been incorporated herein by reference.

Referring to FIGS. 2A and 2B, the electrically isolated electrode terminals 58 are spaced apart over an electrode array surface 82. The electrode array surface 82 and individual electrode terminals 58 will usually have dimensions within the ranges set forth above. In the preferred embodiment, the electrode array surface 82 has a circular cross-sectional shape with a diameter D (FIG. 2B) in the range from 0.3 mm to 10 mm. Electrode array surface 82 may also have an oval shape, having a length L in the range of 1 mm to 20 mm and a width W in the range from 0.3 mm to 7 mm, as shown in FIG. 5. The individual electrode terminals 58 will protrude over the electrode array surface 82 by a distance (H) from 0 mm to 2 mm, preferably from 0 mm to 1 mm (see FIG. 3).

It should be noted that the electrode terminals may be flush with the electrode array surface 82, or the terminals may be recessed from the surface. For example, in dermatological procedures, the electrode terminals 58 may be recessed by a distance from 0.01 mm to 1 mm, preferably 0.01 mm to 0.2 mm. In one embodiment of the invention, the electrode terminals are axially adjustable relative to the electrode array surface 82 so that the surgeon can adjust the distance between the surface and the electrode terminals.

The electrode terminals 58 are preferably composed of a refractory, electrically conductive metal or alloy, such as platinum, titanium, tantalum, tungsten and the like. As shown in FIG. 2B, the electrode terminals 58 are anchored

in a support matrix 48 of suitable insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elk Grove, Ill., because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point.

As shown in FIG. 2A, the support matrix 48 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 48 and the proximal end of probe 10. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy, injection moldable plastic or silicone-based material. In a preferred construction technique, electrode terminals 58 extend through pre-formed openings in the support matrix 48 so that they protrude above electrode array surface 82 by the desired distance H (FIG. 3). The electrodes may then be bonded to the distal surface 82 of support matrix 48, typically by an inorganic sealing material 80. Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the ceramic matrix 48 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

In the embodiment shown in FIGS. 2A and 2B, probe 10 includes a return electrode 56 for completing the current path between electrode terminals 58 and power supply 28. Return electrode 56 is preferably an annular member positioned around the exterior of shaft 13 of probe 10. Return electrode 56 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.15 mm to 4 mm. Return electrode 56 extends from the proximal end of probe 10, where it is suitably connected to power supply 28 via connectors 19, 20, to a point slightly proximal of electrode array surface 82, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm.

Return electrode 56 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulative jacket 18 over return electrode 56 prevents direct electrical contact between return electrode 56 and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (e.g., tendon) and an exposed common electrode member 56 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

Return electrode 56 is preferably formed from an electrically conductive material, usually metal, which is selected from the group consisting of stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. The return electrode 56 may be composed of the same metal or alloy which forms the electrode terminals 58 to minimize any potential for corrosion or the generation of electrochemical potentials due to the presence of dissimilar metals contained within an electrically conductive fluid 50, such as isotonic saline (discussed in greater detail below).

As shown in FIG. 2A, return electrode 56 is not directly connected to electrode terminals 58. To complete this cur-

rent path so that terminals 58 are electrically connected to return electrode 56 via target tissue 52, electrically conducting liquid 50 (e.g., isotonic saline) is caused to flow along liquid paths 83. A liquid path 83 is formed by annular gap 54 between outer return electrode 56 and tubular support member 78. An additional liquid path 83 may be formed between an inner lumen 57 within an inner tubular member 59. However, it is generally preferred to form the liquid path 83 near the perimeter of the probe so that the electrically conducting liquid tends to flow radially inward towards the target site 88 (this preferred embodiment is illustrated in FIGS. 8-19). In the embodiment shown in FIGS. 2-5, the liquid flowing through inner lumen 57 may tend to splash radially outward, drawing electrical current therewith and potentially causing damage to the surrounding tissue.

The electrically conducting liquid 50 flowing through fluid paths 83 provides a pathway for electrical current flow between target tissue 52 and return electrode 56, as illustrated by the current flux lines 60 in FIG. 2A. When a voltage difference is applied between electrode array 12 and return electrode 56, high electric field intensities will be generated at the distal tips of terminals 58 with current flow from array 12 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

FIGS. 2C, 3 and 4 illustrate an alternative embodiment of electrosurgical probe 10 which has a return electrode 55 positioned within tubular member 78. Return electrode 55 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 55. In this embodiment, a voltage difference is applied between electrode terminals 58 and return electrode 55 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60 (FIG. 3). As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 58, tissue 52 becomes ablated or transected in zone 88.

FIG. 2C illustrates the proximal or connector end 70 of probe 10 in the embodiment of FIGS. 3 and 4. Connector 19 comprises a plurality of individual connector pins 74 positioned within a housing 72 at the proximal end 70 of probe 10. Electrode terminals 58 and the attached insulating conductors 42 extend proximally to connector pins 74 in connector housing 72. Return electrode 55 extends into housing 72, where it bends radially outward to exit probe 10. As shown in FIGS. 1 and 2C, a liquid supply tube 15 removably couples liquid source 21, (e.g., a bag of fluid elevated above the surgical site or having a pumping device), with return electrode 55. Preferably, an insulating jacket 14 covers the exposed portions of electrode 55. One of the connector pins 76 is electrically connected to return electrode 55 to couple electrode 55 to power supply 28 via cable 34. A manual control valve 17 may also be provided between the proximal end of return electrode 55 and supply tube 15 to allow the surgical team to regulate the flow of electrically conducting liquid 50.

FIG. 6 illustrates another embodiment of probe 10 where the distal portion of shaft 13 is bent so that electrode terminals extend transversely to the shaft. Preferably, the distal portion of shaft 13 is perpendicular to the rest of the shaft so that electrode array surface 82 is generally parallel to the shaft axis, as shown in FIG. 6. In this embodiment, return electrode 55 is mounted to the outer surface of shaft 13 and is covered with an electrically insulating jacket 18. The electrically conducting fluid 50 flows along flow path 83

through return electrode 55 and exits the distal end of electrode 55 at a point proximal of electrode surface 82. The fluid is directed exterior of shaft to electrode surface 82 to create a return current path from electrode terminals 58, through target tissue 52, to return electrode 55, as shown by current flux lines 60.

FIG. 7 illustrates another embodiment of the invention where electrosurgical system 11 further includes a liquid supply instrument 64 for supplying electrically conducting fluid 50 between electrode terminals 58 and return electrode 55. Liquid supply instrument 64 comprises an inner tubular member or return electrode 55 surrounded by an electrically insulating jacket 18. Return electrode 55 defines an inner passage 83 for flow of fluid 50. As shown in FIG. 7, the distal portion of instrument 64 is preferably bent so that liquid 50 is discharged at an angle with respect to instrument 64. This allows the surgical team to position liquid supply instrument 64 adjacent electrode surface 82 with the proximal portion of supply instrument 64 oriented at a similar angle to probe 10.

FIGS. 8 and 9 illustrate another embodiment of probe 10 where the return electrode is an outer tubular member 56 that circumscribes support member 78 and conductors 42. Insulating jacket 18 surrounds tubular member 56 and is spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 9). Annular gap preferably has a width in the range of 0.15 mm to 4 mm. Ribs 96 can be formed on either the jacket 18 or member 56. The distal end of return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 8, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with the return electrode) and is discharged through the distal end of gap 54. The liquid 50 is then directed around support member 78 to electrode terminals 58 to provide the current pathway between the electrode terminals and return electrode 56. Since return electrode 56 is proximally recessed with respect to electrode surface 82, contact between the return electrode 56 and surrounding tissue is minimized. In addition, the distance L_1 between the active electrode terminals 58 and the return electrode 56 reduces the risk of current shorting therebetween.

The present invention is not limited to an electrode array disposed on a relatively planar surface at the distal tip of probe 10, as described above. Referring to FIGS. 12-14, an alternative probe 10 includes a pair of electrodes 58a, 58b mounted to the distal end of shaft 13. Electrodes 58a, 58b are electrically connected to power supply as described above and preferably have tips 100a, 100b with a screwdriver or flattened shape. The screwdriver shape provides a greater amount of "edges" to electrodes 58a, 58b, to increase the electric field intensity and current density at the edges and thereby improve the cutting ability as well as the ability to limit bleeding from the incised tissue (i.e., hemostasis).

As shown in FIG. 12, current flows between electrode tips 100a and 100b as indicated by current flux lines 60 to heat the target tissue 52. The surgeon then moves probe 10 transversely across tissue 52 to effect an incision 102 in tissue 52, as shown in FIG. 14.

Other modifications and variations can be made to disclose embodiments without departing from the subject invention as defined in the following claims. For example, shaft 13 of probe 10 may have a variety of configurations

other than the generally linear shape shown in FIGS. 1-8. For example, shaft 13 may have a distal portion that is angled, in the range of 10° to 30° (FIG. 10) or 90° (FIGS. 11 and 6), to improve access to the operative site of the tissue 52 being ablated or cut (see FIG. 10). A shaft having a 90° bend angle may be particularly useful for accessing gingiva located in the back portion of the patient's mouth and a shaft having a 10° to 30° bend angle may be useful for accessing gingiva near or in the front of the patient's mouth.

In addition, it should be noted that the invention is not limited to an electrode array comprising a plurality of active electrodes. The invention could utilize a plurality of return electrodes, e.g., in a bipolar array or the like. In addition, depending on other conditions, such as the peak-to-peak voltage, electrode diameter, etc., a single active electrode may be sufficient to develop a vapor layer and induce the discharge of energy to ablate or cut tissue, as described above.

By way of example, FIGS. 21 and 22 illustrate the design of a probe 10 according to the present invention comprising a single active electrode 58 having a tubular geometry. As described above, the return electrode may be an outer tubular member 56 that circumscribes insulated conductor 42 and adhesive bonding material 79 which, in turn, adhesively joins to active electrode support members 48a and 48b. Electrode support members 48a and 48b may be ceramic, glass ceramic or other electrically insulating material which resists carbon or arc tracking. A preferred electrode support member material is alumina. In the example embodiment, a solid rod of alumina forms an inner portion 48b of electrode support member 48 and a hollow tube of alumina forms an outer portion 48a of electrode support member 48. Tubular shaped active electrode 58 may be fabricated using shaped cylinder of this metal comprising an electrically conductive metal, such as platinum, tantalum, tungsten, molybdenum, columbium or alloys thereof. Active electrode 58 is connected to connector 19 (see FIG. 2C) via an insulated lead 108. An electrically insulating jacket 18 surrounds tubular member 56 and may be spaced from member 56 by a plurality of longitudinal ribs 96 to define an annular gap 54 therebetween (FIG. 22). Annular gap 54 preferably has a width in the range of 0.15 to 4 mm. Ribs 96 can be formed on either jacket 18 or tubular member 56. The distal end of the return electrode 56 is a distance L_1 from electrode support surface 82. Distance L_1 is preferably about 0.5 mm to 10 mm and more preferably about 1 to 10 mm. The length L_1 of return electrode 56 will generally depend on the electrical conductivity of the irrigant solution.

As shown in FIG. 21, electrically conducting liquid 50 flows through annular gap 54 (in electrical communication with return electrode 56) and is discharged through the distal end of gap 54. The liquid 50 is then directed around electrode support member 48a to electrode terminal 58 to provide the current pathway between electrode terminal 58 and return electrode 56. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

FIGS. 23 and 24 illustrate further embodiments of electrosurgical probes according to the present invention. In FIG. 23, a probe 10 comprises a multiplicity of electrodes 58 which converge to a single electrode lead 42. As shown, a central electrode 105 extends to the proximal end of the probe shaft for connection to connector 19 (FIG. 2C). The remainder of the electrodes 58 extend through a portion of the probe shaft and are electrically coupled to central electrode 105 by, for example, a weld, solder joint or crimp connection 100. In FIG. 24, an electrosurgical probe 10

comprises a single electrode 58 connected to a single electrode lead 42. As described above, the active and return electrodes are connected to voltage supply 28 via cable 34 (see FIG. 1).

Both of the single active electrode configurations depicted in FIGS. 21-24 may be used with the integral supply means and return electrodes described above in FIGS. 2-11, 30 and 31. Alternatively, these probe configurations may be operated in body cavities already containing an electrically conducting liquid 50, obviating the need for either an integral supply of said liquid or an electrically insulating sleeve to form a conduit for supply of the electrically conducting liquid 50. Instead, an electrically insulating covering would be applied to substantially all of the return electrode 56 (other than the proximal portion).

FIG. 15 illustrates the current flux lines associated with an electric field 120 applied between the active and return electrodes 56, 58 when a voltage is applied therebetween. As shown, the electric field intensity is substantially higher in the region 88 at the tip of the electrode 58 because the current flux lines are concentrated in these regions. This high electric field intensity leads to induced molecular breakdown of the target tissue through molecular dissociation. Preferably, the electric field intensity is sufficient to ionize the vaporized electrically conducting liquid 50 in a thin layer 124 between the distal tip 122 of the active electrode 58 and the target tissue 52, as shown in FIG. 16. The vapor layer 124 will usually have a thickness of about 0.02 to 2.0 mm.

As shown in FIG. 16, the electric field ionizes the vapor layer due to the presence of an ionizable species (e.g., sodium) within the vapor layer to create a plasma. This ionization, under optimal conditions, induces the discharge of highly energetic electrons and/or photons from the vapor layer. The photon and/or the energetic electrons cause disintegration of the tissue molecules adjacent to the vapor layer. FIG. 16 illustrates the issuance of bubbles 126 of non-condensable gaseous products resulting from the disintegration of tissue at the target site.

The system and method of the present invention is also useful in dermatological procedures, i.e., surface tissue ablation on the patient's outer skin or epidermis. For example, the probe of the present invention can be used for the removal of tissue abnormalities, pigmentations, such as freckles, tattoos, age or liver spots, birth marks, malignant melanomas, and superficial lentigines in the epidermis, and other unwanted tissue, such as soft fatty tissue, cutaneous angiodysplasia, e.g., skin anglioma, malignant tumor tissue, lumbago (i.e., tissue bulges extending from the vertebrae) or the like. In addition, the probe of the present invention may be used for removing surface layers of the epidermis to provide younger looking skin (tissue rejuvenation) or for incising, dividing and resecting tissue during cosmetic surgery procedures.

FIG. 17 illustrates an exemplary embodiment, where an electrosurgical probe 130 is utilized to remove the surface layers of the epidermis 140. Probe 130 includes a shaft 132 coupled to a proximal handle 134 for holding and controlling shaft 132. Similar to previous embodiments, probe 130 includes an active electrode array 136 at the distal tip of shaft 132, an annular return electrode 138 extending through shaft 132 and proximally recessed from the active electrode array 136 and an annular lumen 142 between return electrode 138 and an outer insulating sheath 144. Probe 130 further includes a liquid supply conduit 146 attached to handle 134 and in fluid communication with lumen 142 and a source of electrically conducting fluid (not shown) for

delivering the fluid past return electrode 138 to the target site on the epidermis 140. As discussed above, electrode array 136 is preferably flush with the distal end of shaft 132 or distally extended from the distal end by a small distance (on the order of 0.005 inches) so to minimize the depth of ablation. Preferably, the distal end of shaft 132 is beveled to improve access and control of probe 130 while treating the epidermal tissue.

The voltage will preferably be sufficient to establish high electric field intensities between the active electrode array 136 and the epidermal tissue 140 to thereby induce molecular breakdown or disintegration of several cell layers of the epidermal tissue. As described above, a sufficient voltage will be applied to develop a thin layer of vapor within the electrically conducting fluid and to ionize the vaporized layer or region between the active electrode(s) and the target tissue. Energy in the form of photons and/or energetic electrons are discharged from the vapor layer to ablate the epidermal tissue, thereby minimizing necrosis of surrounding tissue and underlying cell layers, such as cell structures in the stratum lucidum and/or stratum granulosum.

FIGS. 18-20 illustrate an exemplary embodiment of another important application of the present invention. As discussed above, the probe of the present invention may be particularly useful for boring a channel through tissue by axially translating the probe towards the tissue as the tissue is disintegrated by the mechanisms discussed above. In the exemplary embodiment, the probe of the present invention is used in a transmyocardial revascularization procedure to form channels from the myocardium to the ventricular cavity to perfuse the myocardium. This procedure is an alternative to coronary artery bypass surgery for treating coronary artery disease. The channels allow oxygen enriched blood flowing into the ventricular cavity from the aorta to directly flow into the myocardium; rather than exiting the heart and then flowing back into the myocardium through the coronary arteries.

As shown in FIG. 18, electrosurgical probe 10 is positioned into one of the ventricular cavities of the heart, in this case, the right ventricle 200. Electrosurgical probe 10 may be introduced into the right ventricle 200 in a variety of procedures that are well known in the art, such as a thoracotomy, sternotomy or minimally invasive procedures. In the representative embodiment, probe 10 is introduced into the vasculature of the patient through a percutaneous penetration and axially translated via a guide catheter 202 through one of the major vessels to the right ventricular cavity 204. A preferred embodiment incorporates a steerable guide catheter 202 which can be externally controlled by the surgeon to direct the distal portion of the guide catheter 202 and probe 10 to the target site(s) in ventricular cavity 204.

Referring to FIG. 19, ventricle wall 206 comprises an epicardium 208, a myocardium 210 and an endocardium 212. In the representative embodiment, probe 10 will form a channel 214 or artificial vessel from the ventricular cavity 206, through the endocardium 212 and into the myocardium 210 to thereby increase myocardial blood flow from the endocardium 212 to the myocardium 210. The location of channel 214 may be selected based on familiar epicardial anatomic landmarks, such as the epicardial branches of the coronary arteries. Guide catheter 202 is positioned adjacent the inner endocardial wall and probe 10 is axially translated so that the active electrode 58 at its distal end is positioned proximate the heart tissue. In this embodiment, the probe includes a single, annular electrode 58 at its distal tip for ablation of the heart tissue. However, it will be readily recognized that the probe may include an array of electrode terminals as described in detail above.

Electrically conducting liquid 50 is delivered through an annular lumen 220 between an annular return electrode 222 and an insulating sheath 224 of the probe. Return electrode 222 is recessed from the distal end of active electrode 58, preferably about 0.025 to 0.050 inches. Alternatively, the return electrode may be positioned on the exterior surface (skin) of the patient, or it may be located nearby on a more proximal position of the probe. Similar to the above embodiments, a high frequency voltage (e.g., 100 kHz) is applied between active electrode(s) 58 and return electrode 222 to establish a current flow therebetween that ablates or disintegrates the heart tissue. The high frequency voltage will preferably be sufficient to vaporize a thin layer of the electrically conducting liquid and to induce the discharge of photon and/or electron energy from the vapor layer to provide cold ablation of the heart tissue.

Ablation of the tissue may be facilitated by axially reciprocating and/or rotating the probe within guide catheter 202 a distance of between about 0.05 to 0.20 inches. This axial reciprocation or rotation allows the electrically conducting liquid 50 to flow over the tissue surface being canalized, thereby cooling this tissue and preventing significant thermal damage to the surrounding tissue cells.

FIG. 20 illustrates an alternative embodiment of the probe of FIG. 1. In this embodiment, the probe 260 includes a central lumen 262 having a proximal end attached to a suitable vacuum source (not shown) and an open distal end 266 for aspirating the target site. The active electrode is preferably a single annular electrode 268 surrounding the open distal end 266 of central lumen 262. Central lumen 262 is utilized to remove the ablation products (e.g., liquids and gases) generated at the target site and excess electrically conductive irrigant during the procedure.

In both of the above embodiments, the present invention provides localized ablation or disintegration of heart tissue to form a revascularization channel 214 of controlled diameter and depth. Usually, the diameter will be in the range of 0.5 mm to 3 mm. Preferably, the radio frequency voltage will be in the range of 400 to 1400 volts peak-to-peak to provide controlled rates of tissue ablation and hemostasis while minimizing the depth of necrosis of tissue surrounding the desired channel. This voltage will typically be applied continuously throughout the procedure until the desired length of the channel 214 is completely formed. However, the heartbeat may be monitored and the voltage applied in pulses that are suitably timed with the contractions (systole) of the heart.

It should be noted that the above embodiment is merely representative and is not intended to limit the invention. For example, the electrosurgical probe can be used to effect a myocardial revascularization channel from the exterior of the heart into the ventricular cavity. In this procedure, the probe will be introduced into the thoracic cavity and positioned adjacent the epicardial layer of one of the ventricular walls via one of a variety of conventional manners. The above electrosurgical procedure will then be performed as the electrode is translated towards the heart until a channel is formed to the ventricular cavity.

The system and method of the present invention may also be useful to efficaciously ablate (i.e., disintegrate) cancer cells and tissue containing cancer cells, such as cancer on the surface of the epidermis, eye, colon, bladder, cervix, uterus and the like. The present invention's ability to completely disintegrate the target tissue can be advantageous in this application because simply vaporizing cancerous tissue may lead to spreading of viable cancer cells (i.e., seeding) to

other portions of the patient's body or to the surgical team in close proximity to the target tissue. In addition, the cancerous tissue can be removed to a precise depth while minimizing necrosis of the underlying tissue.

What is claimed is:

1. A method for applying energy to a target site on a patient body structure comprising:
 - providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
 - positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal; and
 - applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.
2. The method of claim 1 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.
3. The method of claim 2 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm².
4. The method of claim 2 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².
5. The method of claim 2 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0 mm.
6. The method of claim 2 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.
7. The method of claim 2 wherein the electrode terminals comprises a material with a relatively low thermal conductivity.
8. The method of claim 7 wherein the electrode materials comprises a material selected from the group consisting of titanium, tungsten, platinum, aluminum and tantalum.
9. The method of claim 2 wherein the return electrode has a distal end positioned proximal to the electrode array.
10. The method of claim 2 wherein the electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.
11. The method of claim 2 wherein the electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.
12. The method of claim 11 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.
13. The method of claim 1 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.
14. The method of claim 1 wherein at least a portion of the energy is in the form of energetic electrons.
15. The method of claim 14 wherein the energy of the energetic electrons is sufficient to cause disassociation or disintegration of molecules of the body structure.
16. The method of claim 14 wherein the energy evolved by the energetic electrons is greater than 3 eV.
17. The method of claim 1 wherein the high frequency voltage is at least 200 volts peak to peak.
18. The method of claim 1 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

19. The method of claim 1 wherein the electrode terminal is positioned between 0.02 to 5 mm from the target site.

20. The method of claim 1 wherein the vapor layer has a thickness of about 0.02 to 2.0 mm.

21. The method of claim 1 wherein the distance between the most proximal portion of the electrode terminal and the most distal portion of the return electrode is in the range from 0.5 to 10 mm.

22. The method of claim 1 wherein the electrode terminal and the return electrode are of comparable size and comprise a bipolar array of isolated electrode terminals which both come in close proximity or in contact with the body structure.

23. The method of claim 1 wherein the liquid phase of the electrically conducting fluid has a conductivity greater than 2 mS/cm.

24. The method of claim 1 wherein the liquid phase of the electrically conductive fluid comprises isotonic saline.

25. The method of claim 1 wherein the electrode height of the most distal portion of the electrode terminal relative to the most proximal portion of the electrode terminal exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

26. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being in the range from 500 to 1400 volts peak to peak.

27. The method of claim 26 wherein the high frequency voltage is in the range from 700 to 900 volts peak to peak.

28. A method for applying energy to a target site on a patient body structure comprising:

providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source; positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate the body structure without causing substantial tissue necrosis below the surface of the body structure underlying the ablated body structure.

29. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal; and inducing the discharge of photons to the target site in contact with the vapor layer.

30. The method of claim 28 wherein the applying step comprises:

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the active electrode surface; and

inducing the discharge of energetic electrons to the target site in contact with the vapor layer.

31. The method of claim 28 wherein the depth of necrosis is 0 to 400 microns.

32. A method for applying energy to a target site on a patient body structure comprising:

providing an active electrode electrically coupled to a high frequency voltage source;

positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and

generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that cause the breakdown of tissue through molecular dissociation or disintegration.

33. The method of claim 32 wherein the generating step comprises:

providing a return electrode electrically coupled to a high frequency voltage source;

applying a high frequency voltage between the electrode terminal and the return electrode; and

vaporizing the electrically conducting fluid in a thin layer over at least a portion of the electrode terminal.

34. The method of claim 33 further comprising developing a film layer of vapor between the active electrode and the body structure at the target site.

35. The method of claim 33 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

36. The method of claim 35 wherein the cooling step includes translating the distal surface of the electrode terminal over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

37. The method of claims 1 and 28 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

38. The method of claim 37 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

39. The method of claim 37 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.

40. The method of claim 37 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.

41. The method of claims 28 and 32 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

42. The method of claim 41 wherein the generating step comprises:

providing a return electrode electrically coupled to a higher frequency voltage source;

applying a high frequency voltage between the return electrode and the array of electrode terminals; and

vaporizing the electrically conducting fluid in a thin layer over one or more of the electrode terminals of the array.

43. The method of claim 42 further comprising developing a film layer of vapor between one or more of the electrode terminals and the target site.

44. The method of claim 42 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

45. The method of claims 1 and 33 wherein the density of the vapor layer is less than about 10^{20} atoms/cm³.

46. The method of claims 1 and 30 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 1 and 28 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

48. The method of claims 26 and 28 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 26 and 28 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

50. The method of claims 26 and 28 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.

51. The method of claims 26 and 28 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

52. The method of claims 1 and 28 further comprising cooling the tissue with the electrically conducting fluid to

reduce the temperature rise of those portions of the body structure adjacent the target site.

53. The method of claim 52 wherein the cooling step includes translating the distal surface of the active electrode over the target site to allow the electrically conducting fluid to contact the tissue after the tissue has been subjected to the electric field.

54. The method of claims 1 and 28 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

55. The method of claims 1 and 28 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 26 and 28 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers, et. al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

23. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode terminal in close proximity to the target site in the presence of an electrically conducting [terminal] fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Signed and Sealed this
Seventh Day of April, 1998

Attest:



Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 24, lines 6-18, claim 1, should read as follows:

1. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

This certificate supersedes Certificate of Correction issued April 7, 1998.

Signed and Sealed this
Twenty-fifth Day of August, 1998



Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882

Page 1 of 2

DATED : December 16, 1997

INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

37. The method of claims 23 or 48 wherein the electrode terminal is surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate the proximal portion of the electrode terminal from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

45. The method of claims 23 or 55 wherein the density of the vapor layer is less than about 10^{20} atoms/cm³.

46. The method of claims 23 or 50 wherein the electrode terminal is configured to promote bubble nucleation causing the formation of the vapor layer.

47. The method of claims 23 or 48 wherein the electrode terminal has a contact surface area in the range of about 0.25 mm² to 50 mm².

48. The method of claims 48 or 52 wherein the high frequency voltage is at least 200 volts peak to peak.

49. The method of claims 48 or 52 wherein the high frequency voltage is in the range from about 500 to 1400 volts peak to peak.

50. The method of claims 48 or 52 wherein the electrode terminal is positioned between 0.02 to 2.0 mm from the target site.

51. The method of claims 48 or 52 wherein the electrode terminal and the return electrodes comprise a bipolar array of isolated electrode terminals.

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers et al.

Page 2 of 2

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

52. The method of claims 23 or 48 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.

54. The method of claims 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.

55. The method of claims 23 or 48 wherein the target site is a tumor within or on the patient's body.

56. The method of claims 48 or 52 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

Signed and Sealed this
Second Day of May, 2000

Attest:



Q. TODD DICKINSON

Attesting Officer

Director of Patents and Trademarks

United States Patent [11]

Roos

[11] 4,116,198

[45] Sep. 26, 1978

[34] ELECTRO-SURGICAL DEVICE

- [75] Inventor: Eberhard Roos, Tuttingen, Fed. Rep. of Germany
 [73] Assignee: DELMA, elektro und medizinische Apparatebau-Gesellschaft m.b.H., Tuttingen, Fed. Rep. of Germany

[21] Appl. No.: 686,608

[22] Filed: May 14, 1976

[30] Foreign Application Priority Data

May 15, 1975 [DE] Fed. Rep. of Germany — 2521719

[51] Int. Cl.² A61B 17/32

[52] U.S. Cl. 128/303.15

[58] Field of Search 128/303.11-303.18

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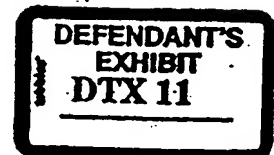
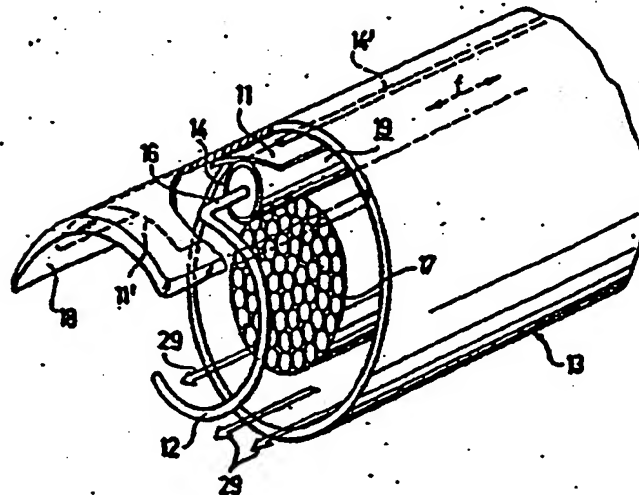
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Primary Examiner—Lee S. Cohen

[57] ABSTRACT

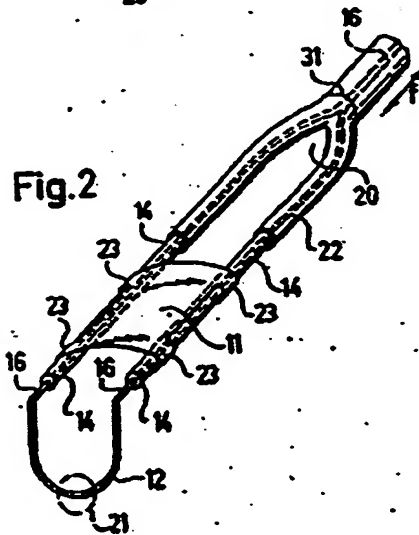
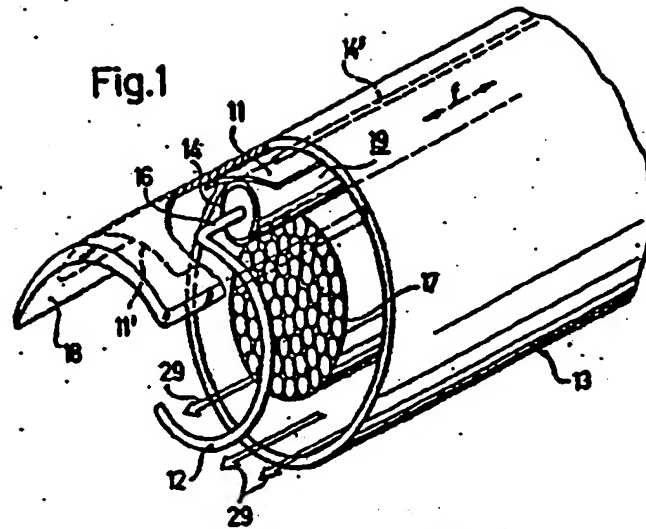
Electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue, wherein the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope.

20 Claims, 9 Drawing Figures

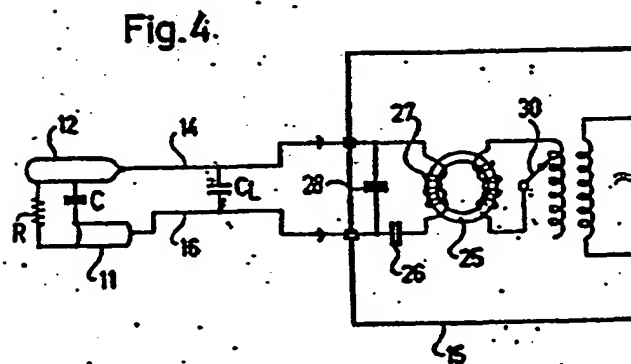
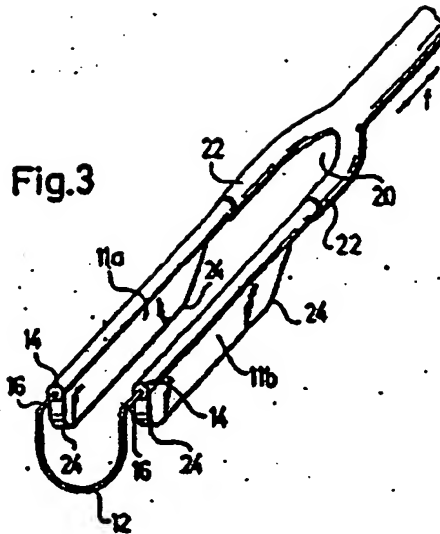


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Fig. 5

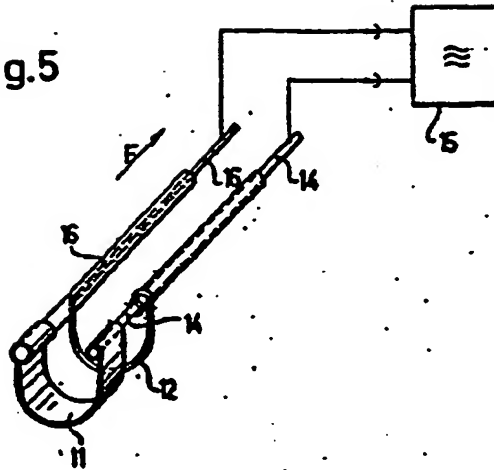
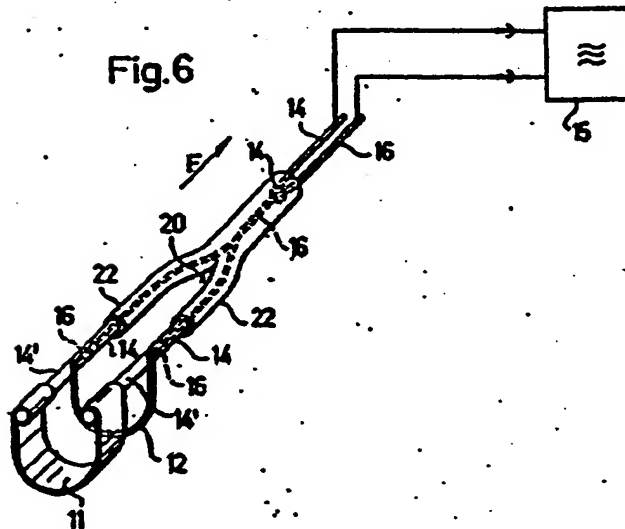
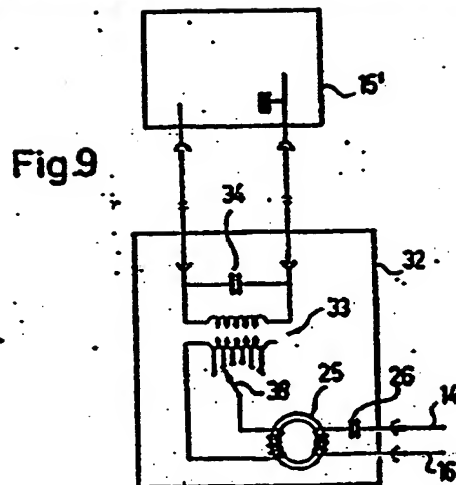
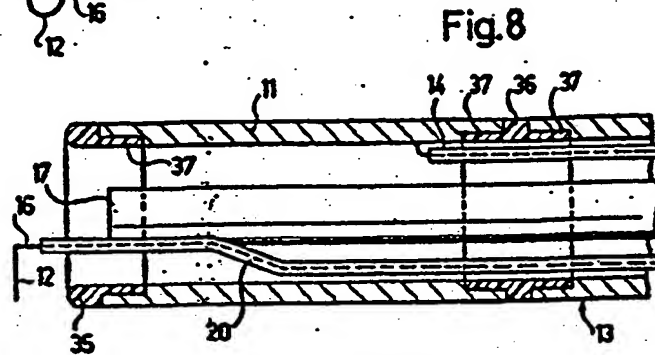
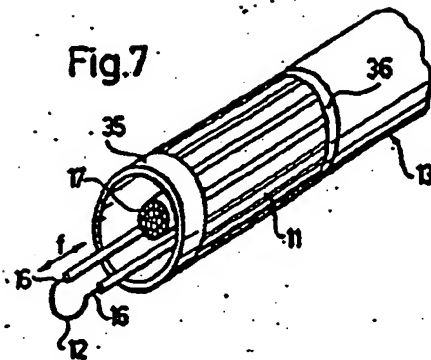


Fig. 6



S&N0000433



S&N0000434

ELECTRO-SURGICAL DEVICE

BACKGROUND OF THE INVENTION

The invention relates to an electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area, neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue.

Electro-surgical devices of this type permit electro-surgical operations of the filled bladder (electro-resection, e.g. of bladder tumors and the prostate glands) using endoscopes, particularly resectoscopes and cystoscopes.

The high degree of development in the endoscope field has resulted in operations in the bladder and on the prostate glands using these instruments and by means of electro-surgery have become the most commonly used operating procedure.

In known devices of this type, high frequency alternating current is fed via an earthed neutral electrode on the one hand and via a sparking ball or cutting loop well insulated relative to the outer shaft of the endoscope on the other to the operating area for coagulation purposes in the case of hemorrhages. Due to the relatively small area of the cutting loop compared to the area of the neutral electrode applied externally to the patient's body a very high current density occurs in the area of the cutting loop which results in heat generation in the tissue linked with the bursting of the tissue cells through steam generation and consequently a separation of the tissues. For the desired cutting or coagulating effects, the necessary power values of the high frequency current applied vary between 120 and 150 W.

As the leads from the high frequency generator to the cutting electrode have to be passed through the metallic endoscope, the distances between the high frequency-carrying lead and the remaining metal parts of the endoscope insulated therefrom are so small that capacitances of considerable size exist between these metal parts. Thus, to a certain extent, the endoscope forms a capacitor via which part of the applied capacity flows away as leakage current onto the tissues engaging with the metal endoscope shaft. A further, still larger portion of the applied capacity flows from the cutting loop via the washing water directly to the metal parts of the endoscope shaft located in the washing water flow and from there to the engaging tissue. Thus, uncontrollable electrical conditions in the urethral tissue engaging with the endoscope and the unequal distribution of lubricants with insulating properties on the endoscope shaft can cause critical current densities when the leakage current passes to the urethra and this results in burns.

These difficulties would not be eliminated by coating the endoscope shaft with tubes of high-grade insulating material, because the slightest damage to the shaft insulation due to the very high current densities occurs during the passage of the leakage current would, in fact, increase the danger of burning due to the damage. However, if the endoscope shaft insulation remains intact,

the entire leakage current is led off to the points where the operator is in contact with the endoscope leading to burns to the operator's face or to the eye in contact with the metal escutcheons of the transparent optics.

Neutral electrode isolation from earth potential cannot prevent the passage of the leakage currents to the operator. As the neutral electrode acts as an opposite pole to the cutting or coagulation electrode between the patient and the earthed operating table, it is capacitively connected to earth potential. Therefore, the cutting loop and the leakage current flows therefrom together with its voltage are earthed. Since, in any case, the operator largely carries the earth potential, the passage of the leakage current to the operator cannot be avoided by the measures in question.

BRIEF SUMMARY OF THE INVENTION

The problem of the invention is therefore to provide an electro-surgical device of the type indicated hereinbefore where undesired burns to the urethra and the operator are effectively avoided.

According to the invention, this problem is solved in that the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope. In this way, potential compensation takes place in a spatially very narrowly defined zone. Both the treatment electrode, preferably constructed as a cutting loop and the neutral electrode carry no potential to earth. Leakage current does not flow to the endoscope shaft either from the high frequency lead to the treatment electrode or from the lead to the neutral electrode. Due to the existing capacitance, leakage currents only flow between the leads, but these do not have any external effects.

However, due to the small-area construction of the treatment electrode, a high current density is obtained there, which is adequate for tissue separation or coagulation, whereas the neutral electrode arranged in the immediate vicinity has such a large area that undesired heating is avoided there.

According to a preferred embodiment, the two feed leads comprise a coaxial cable, whose shield forms one conductor and is insulated relative to the endoscope. Thus, the two high frequency leads for the treatment and neutral electrode form a structural unit, which whilst taking up only a small amount of space, can be simply passed through the endoscope together with the optical and washing portions.

In general, the treatment electrode should be in loop form so that the operator's field of vision is unobstructed.

According to a further embodiment, the centre conductor of the coaxial cable at the front projects above the shield and at this point passes into the treatment electrode. It is thereby particularly advantageous if the shield is constructed as a rigid sleeve and in such a way that the treatment electrode can be moved backwards and forwards relative to the endoscope via the coaxial cable. Thus, in this embodiment, the coaxial cable at the same time forms the support and operating member for the treatment electrode.

The relatively large neutral electrode is advantageously directly fixed to the coaxial cable shield. In this way the neutral electrode can be mounted reliably and immovably in an inexpensive and uncomplicated manner.

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Advantageously, the neutral electrode is constructed as an elongated metal sheet slightly curved about the endoscope shaft and extending on either side over the coaxial cable.

According to a further advantageous embodiment, the endoscope has a plastic extension extending over a small portion only of its periphery, whereby the treatment electrode can be moved backwards and forwards beneath the said extension. This plastic extension has the advantage that the washing liquid can be satisfactorily guided and tissue which is not to be treated can be kept away from the treatment electrode. According to the invention, this extension can be used so that the large-area neutral electrode is fixed in insulated manner relative to the endoscope on the inside of the extension. The neutral electrode is then preferably connected with the high frequency generator by an insulated cable secured in the endoscope. In this case, only the other conductor with its insulation and treatment electrode is axially movable.

According to a particularly preferred embodiment, the coaxial cable has a bifurcation just before the body-side end of the endoscope and the two inner conductors emanating from the bifurcation are interconnected by a loop forming the treatment electrode. This construction is particularly stable due to the symmetry conditions resulting from the bifurcation, whereby at the same time the operator still has good visibility through the cutting loop forming the treatment electrode.

If the treatment electrode is used for coagulation purposes, a coagulation sparking ball is fixed to the treatment electrode.

The coaxial cable is advantageously surrounded by an insulating lead so as to prevent any connection of the endoscope metal with the high frequency voltage. Preferably, the insulating sleeve of the bifurcated coaxial cable is also bifurcated, but it extends only so just in front of the neutral electrode.

In the case of the bifurcated coaxial cable, the neutral electrode is preferably an elongated metal sheet, bent slightly around the endoscope shaft and extending from one branch of the bifurcation to the other. The sheet can have projections at the four corners which are placed around the shields. Depending on the degree of placing around and also clamping, any desired fixing of the neutral electrode to the coaxial cable can be obtained.

The current density in the area of the operating zone is advantageously influenced if the neutral electrode terminates at a distance from the end of the shield.

According to a further advantageous embodiment, the neutral electrode comprises two partial electrodes extending in the direction of the loop away from the two arms of the bifurcation. Preferably, the partial electrodes do not extend quite as far from the shields as the loop. At the front and rear ends the sheets preferably have rounded portions.

As a result of the slide-like construction, the operator can reliably guide the endoscope by placing the slide-like sheet projections on the tissue to then be removed. As is known, the endoscope is operated in such a way that the cutting loop is moved forwards relative to the endoscope, made live and then slowly retracted, whereby the tissue is removed by the heating on the cutting loop.

As stated hereinbefore, the treatment electrode and neutral electrode are appropriately so shaped and pos-

sioned that the illumination, vision and washing operations are not impaired by the endoscope.

Advantageously, the leads are inductively connected to the high frequency generator, whereby advantageously, a capacitor for filtering out low frequency voltage portions is preferably provided in one lead. This, in advantageous manner avoids faradic effects in the muscular system of the patient.

A capacitor is appropriately connected in parallel to the output winding of the transmitter which with the inductor of the latter forms an oscillating circuit which is tuned in such a way that the attenuation in the oscillating circuit formed by the leads, treatment electrode and neutral electrode is minimal.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects of the present invention will be apparent from the following description and claims and are illustrated in the accompanying drawings which, by way of illustration show preferred embodiments of the present invention and the principles thereof and what are now considered to be the best modes contemplated for applying these principles. Other embodiments of the invention embodying the same or equivalent principles may be used and structural changes may be made if desired by those skilled in the art without departing from the invention and the scope of the appended claims.

In the drawings shown:

FIG. 1 a schematic, greatly enlarged perspective view of the front end of an endoscope equipped with the electro-surgical device according to the invention.

FIG. 2 a perspective view of a further embodiment of the electro-surgical device according to the invention, without the endoscope surrounding the same.

FIG. 3 a further embodiment of the electro-surgical device according to the invention, once again without a surrounding endoscope.

FIG. 4 a schematic circuit diagram of the electro-surgical device according to the invention with a particularly suitable high frequency generator.

FIGS. 5 and 6 perspective views of two further advantageous embodiments.

FIGS. 7 and 8 a perspective view and an axial section of a further advantageous embodiment.

FIG. 9 a schematic circuit diagram of an additional device for the device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to FIG. 1, an endoscope 10 is axial traversed in conventional manner by a fibre optical system 17, which is spaced relative to the sides of the endoscope 10, in such a way that washing liquid can pass through there (arrow 23) and there still remains space for the axial insertion of an electro-surgical treatment device.

According to the invention, this electro-surgical treatment device comprises a coaxial cable 19 with rigid metallic shield 14 and an inner conductor 16 axially inserted together with the fibre optical system 17. Inside the metallic shaft of the endoscope 10, the shield 14 is covered in not shown manner with an insulating sleeve 22, shown in the case of the constructions of FIGS. 2 and 3.

At the front, inner conductor 16 projects somewhat from the coaxial cable 19 and passes into the treatment electrode 12, which in general comprises a loop con-

ing free visibility for the operator via the fibre optical systems 17.

The opposite electrode for the cutting electrode 12 is formed by a neutral electrode 11 fixed in electrically conductive manner to shield 14 and which is curved somewhat about the endoscope shaft, having a rectangular, deepened form shown in FIG. 1. Inner conductor 16 and shield 14 are connected, as shown in FIG. 4 to the two poles of a high frequency generator 13 which are not at earth potential.

At the front end of the metal shaft of the endoscope 13 is fixed a plastic extension 18, which is rounded and extends in the manner shown in FIG. 1, so as not to impair insertion, for example into the urethra. As the plastic extension 18 is an insulating body, the large-area neutral electrode 11' can also be fixed to the inside. It is then appropriately connected with the associated pole of the high frequency generator via a separate insulated conductor 14' in the endoscope, inside of via the shield 14.

As a result of the construction according to the invention, a high frequency field is only formed between shield 14 and inner conductor 16, as well as between neutral electrode 11 and treatment electrode 12, as is shown schematically in FIG. 4 by capacitors C_1 and C_2 . Due to the current conduction through the tissue fluid and tissue itself, a true resistor R is also conceivable parallel to the capacitor between neutral electrode 11 and treatment electrode 12.

The supply to connect neutral electrode 11 and the treatment electrode 12 takes place by the inductive coupling of a high frequency voltage by means of a transformer 23, whose input voltage is regulatable by a variable tap 30. Due to the inductive coupling, the output lines 14 and 16 are galvanically isolated from earth potential.

A capacitor 26 connected in lead 16 is used for filtering out the low frequency current and therefore avoids faradic effects in the muscular system of the patient. A capacitor 28 connected in parallel to the output winding 27 of transformer 23 and behind capacitor 26 forms with the output winding an oscillating circuit tuned in such a way that the attenuation in the oscillating circuit formed from C_2 , C and R as well as the inductors of lines 14, 16 is minimal.

As a result of the construction according to the invention, the leakage currents only flow between lines 14, 16 and therefore do not reach the metal shaft of endoscope 13. Thus, larger current densities such as are necessary for tissue separation or coagulation only occur outside the endoscope in the operating area.

Therefore, the danger of heating outside the desired area, as well as burns to the operator is reliably avoided.

FIG. 1 shows a particularly advantageous embodiment of the electro-surgical device according to the invention in which both the inner conductor 16 and the shield 14 have a bifurcation 29. In the same way, the insulating sleeve drawn over the shield 14 is bifurcated. The production of such a bifurcation is advantageously obtained by a welded joint at point 31 indicated by a line.

As a result of the bifurcation shown in FIG. 2, a cutting loop 12 can be arranged in the shown manner between the two inner conductors 16 emanating at the end. If the treatment electrode is to be used for coagulation, a coagulation sparking ball 22 can be provided on loop 12.

The construction of FIG. 2 is particularly well suited to the arrangement of a relatively large-area neutral electrode 11 which appropriately extends between the shields 14 of the two branches of the bifurcation 29, being slightly bent about the endoscope shaft. At the end, the neutral electrode 11 has projections 23 which are securely placed around the shields 14 for securing neutral electrodes 11 and for supplying the same with voltage. The metal sheathing forming the neutral electrode simultaneously constructionally reinforces the bifurcation 29, so that the guidance of the treatment electrode 12 by the operator is aided. As is known, the axial movement of the electro-surgical device in the direction of the double arrow/takes place by operating a pistol-like handle on endoscope 13, not shown in the drawing.

A further advantageous embodiment is shown in FIG. 3 where the neutral electrode is broken up into two partial electrodes 11a, 11b, which in the represented manner are soldered or welded to the shields 14 in such a way that the partial electrodes extend in the same direction as cutting loop 12. Rounded portions 24 are provided at both ends. The partial electrodes 11a, 11b applied to the shields 14 in this way thus additionally form slide-like support, by means of which the electro-surgical device can be placed on the tissue to be removed. This not only ensures a reliable guidance of the device but also ensures that the tissue is removed to the predetermined depth. The electrical advantages of limiting current conduction to the operating area are completely maintained.

FIG. 5 shows a further advantageous embodiment, whereby only the front part of the electro-surgical device without the endoscope is shown. In this embodiment, two insulated cables with inner conductors 14, 16 are passed from high frequency generator 13 through the endoscope. At the front end are successively arranged the cutting loop 12 and the neutral electrode 11 constructed as a steel band. The cutting loop 12 is electrically conductively connected with the inner conductor 16, but at the other end is only fixed to the insulation surrounding the conductor 14. Conversely, the steel band 11, whose shape is similar to the cutting loop 12, is connected in electrically conductive and mechanically secure manner with the inner conductor 14, whilst the opposite end is mechanically secured to the insulation of the inner conductor 16. Since, according to the invention, the steel band 11 has the same radius as the wire loop, on retracting the loop 12 in the direction of arrow F, the band does not form an obstacle to the tissue portions removed by the loop. The neutral electrode 11 in the form of the steel band rests on the tissue in large-area form, so that good electrical contact is ensured.

FIG. 6 shows an embodiment which is substantially the same as FIG. 5, whereby however, a bifurcated coaxial cable, similar to FIGS. 2 and 3 is used. The wire loop 12 is once again fixed to the inner conductors 16, whilst the neutral conductor 11 in band form is mechanically secured to extensions 14' electrically connected with the shield 14.

In the embodiment according to FIGS. 7 and 8, the front portion of endoscope 13 itself or a coaxial connection attached thereto at the front is constructed as the neutral electrode 11. To this end, the front portion is electrically insulated relative to the rear portion or the front-fitted connection from endoscope 13 by an immediately inserted insulating ring 34. The cutting loop 12 can at the front be passed out of the neutral electrode

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11 is one of the above-described manner. In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of endoscope 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator 15 not shown in FIGS. 7 and 8.

It is also important in the case of the embodiments of FIGS. 7 and 8 that the cutting loop extends radially up to an insulating ring 35 mounted at the front on the neutral electrode 11 and can be retracted up to this. In this way, the front edge of the endoscope shaft, namely the front edge of the insulating ring 35 serves as a support for the cutting loop 12, so that the material is reliably removed therefrom. Therefore, as shown the insulating ring 35 must be rounded at the front.

Preferably, the insulating rings 35, 36 have axial attachments 37 with a reduced external diameter, by means of which a mechanically secure fixing to the metal tubes is ensured.

FIG. 9 shows an additional device 32, by means of which a conventional high frequency surgical apparatus 15' with an earthed output terminal can be made usable for the purposes of the invention. The additional device 32 connected to the high frequency apparatus 15' has at the inlet a transformer 33 with parallel-connected capacitor 34 for tuning to the resonant frequency of the output circuit of the high frequency apparatus 15'. The output winding of transformer 33 is preferably regulatable by means of a loop arm 38 in such a way that the inductive output transformer 25 can receive voltages of varying size.

Via a capacitor 26, the output winding of transformer 25 is applied to the two output terminals of the additional device 32, where the leads 14, 16 can be applied.

In this way the high frequency apparatus 15' acquires an output with fluctuating potential, as is necessary for the connection of the electro-surgical device according to the invention.

The invention is not limited to the embodiments described and represented heretofore and various modifications can be made thereto without passing beyond the scope of the invention.

What is claimed is:

1. A combination: an endoscope having an endoscope body of substantially tubular shape, and an electro-surgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.

2. The combination of claim 1, wherein said insulated cable means and said means for connecting said neutral electrode to said other pole comprise coaxial cable means with shielding means forming one of said connecting means and being insulated relative to said endoscope body.

3. The combination according to claim 2, wherein said shielding means is constructed as a rigid sleeve in which said treatment electrode is adapted to be moved back and forth relative to said endoscope body through said coaxial cable means.

4. The combination according to claim 2, wherein said neutral electrode is fixed directly to said shielding means of said coaxial cable means.

5. The combination according to claim 4, wherein the neutral electrode is constructed as an elongated metal sheet slightly bent within said endoscope body and extending over said coaxial cable means.

6. The combination according to claim 2, comprising an insulating sleeve surrounding said coaxial cable means.

7. The combination according to claim 6, wherein said insulating sleeve is bifurcated and extends approximately to said neutral electrode.

8. The combination according to claim 7, wherein said neutral electrode is an elongated metal sheet slightly bent within said endoscope body and extending from one branch of said bifurcated insulating sleeve to the other.

9. The combination according to claim 8, wherein said sheet has projections at its four corners, two each of which are placed around the respective branches of said bifurcated sleeve.

10. The combination according to claim 2, wherein said neutral electrode terminates at a distance from said shielding means.

11. The combination according to claim 1, wherein said neutral electrode is secured to and insulated from said endoscope body on the inside of said insulating projection.

12. The combination according to claim 1, wherein said means for connecting said neutral electrode to said high-frequency generator is an insulated conductor secured in said endoscope body.

13. The combination according to claim 2, wherein said coaxial cable means has a bifurcation at that end of the endoscope body adjacent said projection, two inner conductors extending from said bifurcation, and a loop interconnecting said two inner conductors and forming said treatment electrode.

14. The combination according to claim 1, wherein a coagulation sparking ball is fitted to said treatment electrode.

15. The combination according to claim 1, comprising a high-frequency generator, and wherein said cable means and said connecting means are inductively coupled to said high-frequency generator.

16. The combination according to claim 15, wherein a capacitor is connected in one of said cable means and said connecting means for filtering out low-frequency voltage.

17. The combination according to claim 15, wherein said generator comprises a transformer with an output winding having an inductor, a capacitor being connected parallel to said output winding and forming an oscillating circuit with said inductor, said circuit being tuned such that the attenuation in said circuit formed by said cable means, said connecting means, treatment electrode and neutral electrode is minimal.

18. The combination according to claim 15, comprising means for potential isolation connected between said high-frequency generator and said cable means and said connecting means respectively.

19. The combination according to claim 18, wherein said potential isolation means comprises a transformer, a capacitor connected parallel to said transformer, said high-frequency generator having an output circuit, said

transformer and said output circuit being tuned in resonance.

20. The combination according to claim 19, comprising an inductive transformer connected to said transformer, said cable means and said connecting means being connected to said inductive transformer.

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[54] ELECTRO - SURGICAL DEVICE.

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[51] Int. Cl.² A61B 17/32

[52] U.S. Cl. 128/303.15

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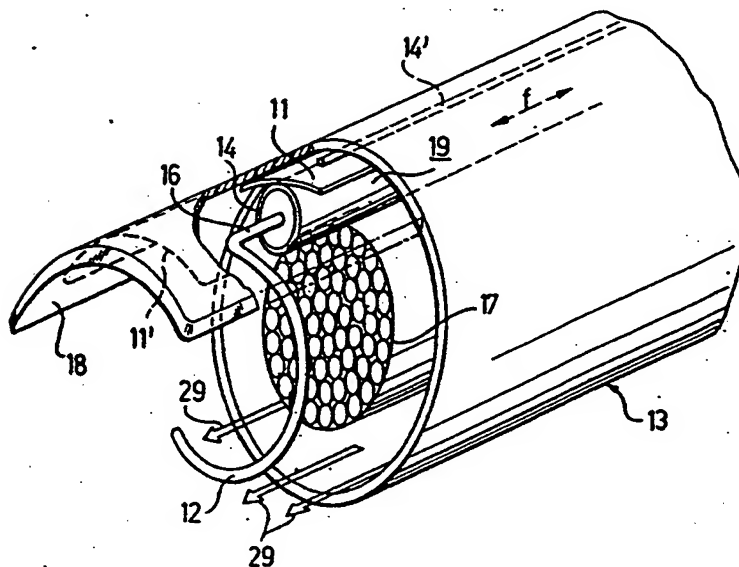
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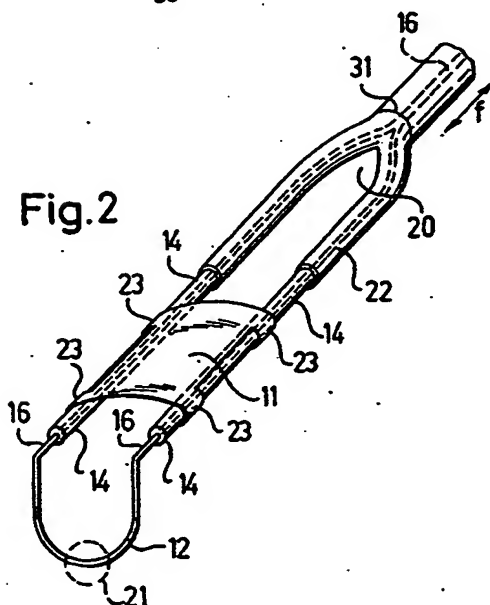
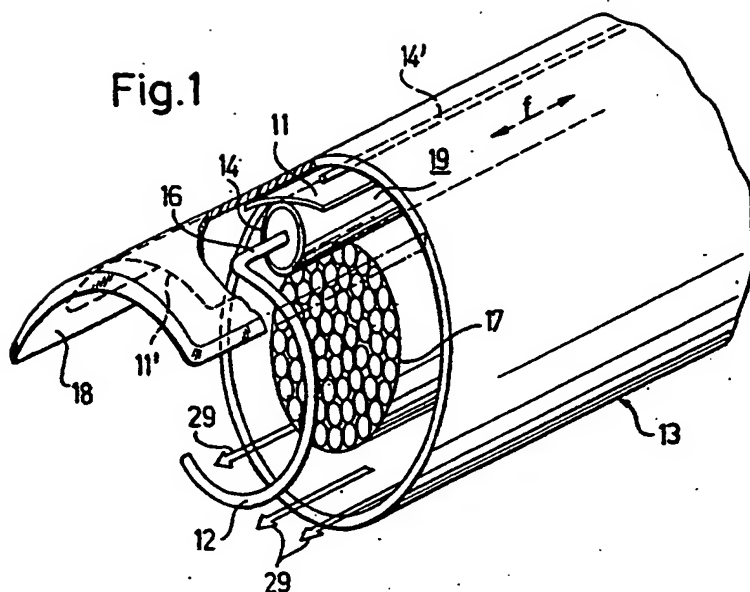
Primary Examiner—Lee S. Cohen

[57] ABSTRACT

Electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue, wherein the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope.

20 Claims, 9 Drawing Figures





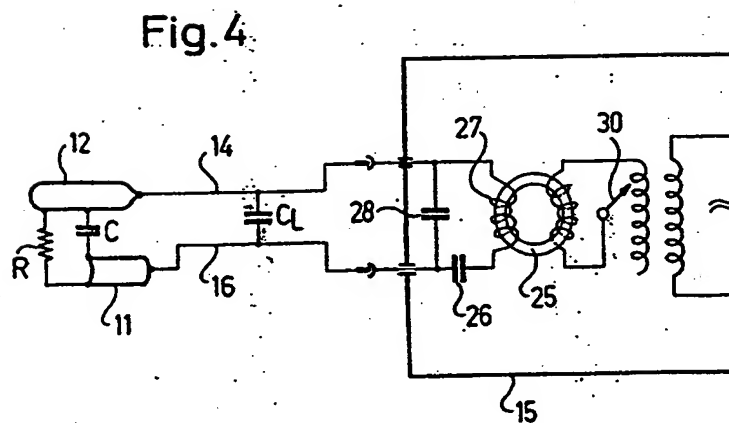
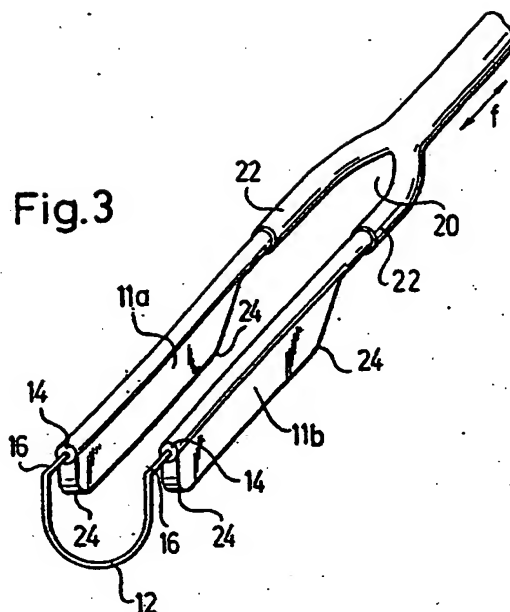


Fig. 5

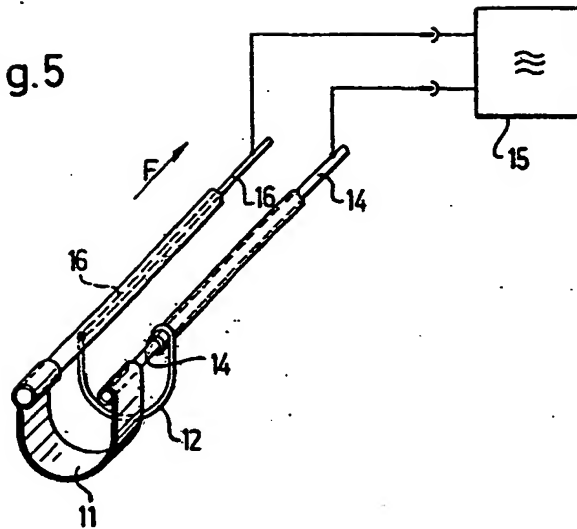
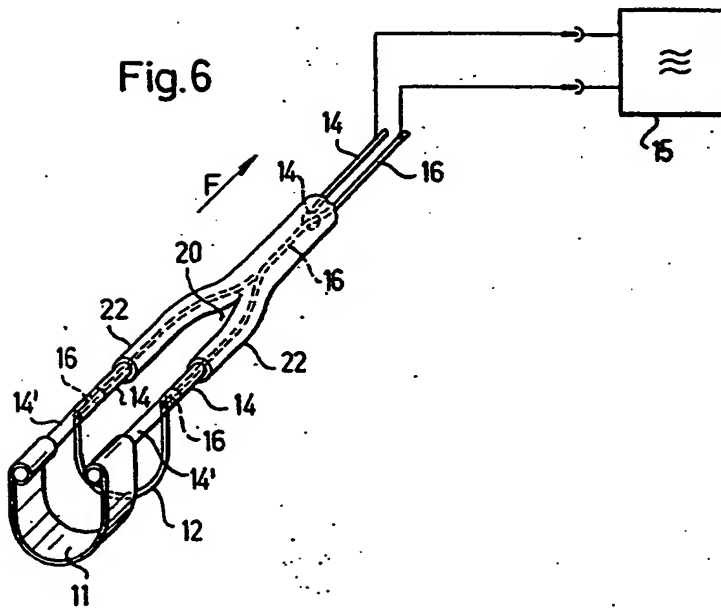
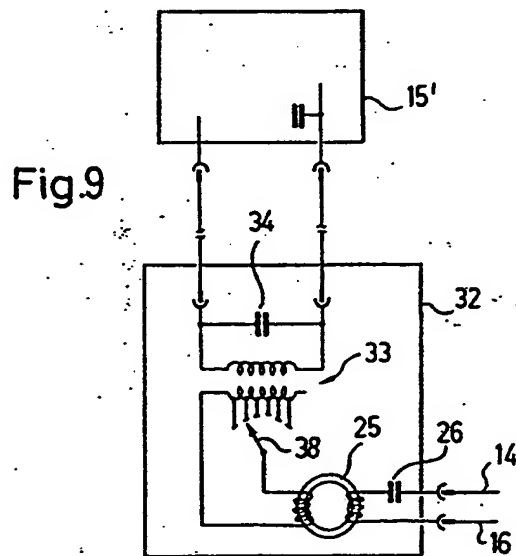
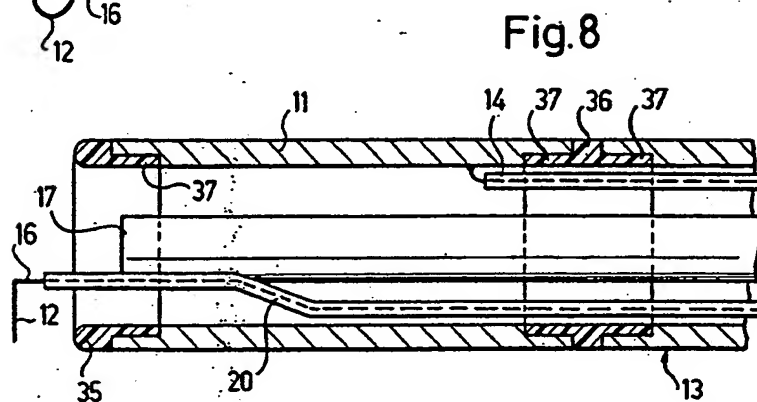
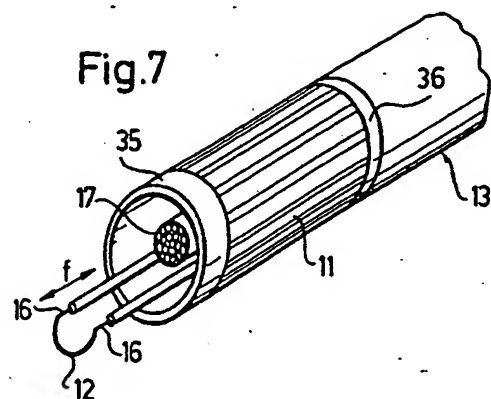


Fig. 6





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ELECTRO - SURGICAL DEVICE

BACKGROUND OF THE INVENTION

The invention relates to an electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue.

Electro-surgical devices of this type permit electro-surgical operations of the filled bladder (electro-resection, e.g. of bladder tumors and the prostate glands) using endoscopes, particularly resectoscopes and cystoscopes.

The high degree of development in the endoscope field has resulted in operations in the bladder and on the prostate glands using these instruments and by means of electro-surgery have become the most commonly used operating procedure.

In known devices of this type, high frequency alternating current is fed via an earthed neutral electrode on the one hand and via a sparking ball or cutting loop well insulated relative to the outer shaft of the endoscope on the other to the operating area for coagulation purposes in the case of hemorrhages. Due to the relatively small area of the cutting loop compared to the area of the neutral electrode applied externally to the patient's body a very high current density occurs in the area of the cutting loop which results in heat generation in the tissue linked with the bursting of the tissue cells through steam generation and consequently a separation of the tissues. For the desired cutting or coagulating effects, the necessary power values of the high frequency current applied vary between 120 and 150 W.

As the leads from the high frequency generator to the cutting electrode have to be passed through the metallic endoscope, the distances between the high frequency-carrying lead and the remaining metal parts of the endoscope insulated therefrom are so small that capacitances of considerable size exist between these metal parts. Thus, to a certain extent, the endoscope forms a capacitor via which part of the applied capacity flows away as leakage current onto the tissue engaging with the metal endoscope shaft. A further, still larger portion of the applied capacity flows from the cutting loop via the washing water directly to the metal parts of the endoscope shaft located in the washing water flow and from there to the engaging tissue. Thus, uncontrollable electrical conditions in the urethral tissue engaging with the endoscope and the unequal distribution of lubricants with insulating properties on the endoscope shaft can cause critical current densities when the leakage current passes to the urethra and this results in burns.

These difficulties would not be eliminated by coating the endoscope shaft with tubes of high-grade insulating material, because the slightest damage to the shaft insulation due to the very high current densities occur during the passage of the leakage current would, in fact, increase the danger of burning due to the damage. However, if the endoscope shaft insulation remains intact,

the entire leakage current is led off to the points where the operator is in contact with the endoscope leading to burns to the operator's face or to the eye in contact with the metal escutcheons of the transparent optics.

Neutral electrode isolation from earth potential cannot prevent the passage of the leakage currents to the operator. As the neutral electrode acts as an opposite pole to the cutting or coagulation electrode between the patient and the earthed operating table, it is capacitively connected to earth potential. Therefore, the cutting loop and the leakage current flown therefrom together with its voltage are earthed. Since, in any case, the operator largely carries the earth potential, the passage of the leakage current to the operator cannot be avoided by the measures in question.

BRIEF SUMMARY OF THE INVENTION

The problem of the invention is therefore to provide an electro-surgical device of the type indicated hereinbefore where undesired burns to the urethra and the operator are effectively avoided.

According to the invention, this problem is solved in that the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope. In this way, potential compensation takes place in a spatially very narrowly defined zone. Both the treatment electrode, preferably constructed as a cutting loop and the neutral electrode carry no potential to earth. Leakage current does not flow to the endoscope shaft either from the high frequency lead to the treatment electrode or from the lead to the neutral electrode. Due to the existing capacitance, leakage currents only flow between the leads, but these do not have any external effects.

However, due to the small-area construction of the treatment electrode, a high current density is obtained there, which is adequate for tissue separation or coagulation, whereas the neutral electrode arranged in the immediate vicinity has such a large area that undesired heating is avoided there.

According to a preferred embodiment, the two feed leads comprise a coaxial cable, whose shield forms one conductor and is insulated relative to the endoscope. Thus, the two high frequency leads for the treatment and neutral electrode form a structural unit, which whilst taking up only a small amount of space, can be simply passed through the endoscope together with the optical and washing portions.

In general, the treatment electrode should be in loop form so that the operator's field of vision is uninterrupted.

According to a further embodiment, the centre conductor of the coaxial cable at the front projects above the shield and at this point passes into the treatment electrode. It is thereby particularly advantageous if the shield is constructed as a rigid sleeve and in such a way that the treatment electrode can be moved backwards and forwards relative to the endoscope via the coaxial cable. Thus, in this embodiment, the coaxial cable at the same time forms the support and operating member for the treatment electrode.

The relatively large neutral electrode is advantageously directly fixed to the coaxial cable shield. In this way the neutral electrode can be mounted reliably and immovably in an inexpensive and uncomplicated manner.

Advantageously, the neutral electrode is constructed as an elongated metal sheet slightly curved about the endoscope shaft and extending on either side over the coaxial cable.

According to a further advantageous embodiment, the endoscope has a plastic extension extending over a small portion only of its periphery, whereby the treatment electrode can be moved backwards and forwards beneath the said extension. This plastic extension has the advantage that the washing liquid can be satisfactorily guided and tissue which is not to be treated can be kept away from the treatment electrode. According to the invention, this extension can be used so that the large-area neutral electrode is fixed in insulated manner relative to the endoscope on the inside of the extension. The neutral electrode is then preferably connected with the high frequency generator by an insulated cable secured in the endoscope. In this case, only the other conductor with its insulation and treatment electrode is axially movable.

According to a particularly preferred embodiment, the coaxial cable has a bifurcation just before the body-side end of the endoscope and the two inner conductors emanating from the bifurcation are interconnected by a loop forming the treatment electrode. This construction is particularly stable due to the symmetry conditions resulting from the bifurcation, whereby at the same time the operator still has good visibility through the cutting loop forming the treatment electrode.

If the treatment electrode is used for coagulation purposes, a coagulation sparking ball is fitted to the treatment electrode.

The coaxial cable is advantageously surrounded by an insulating lead so as to prevent any connection of the endoscope metal with the high frequency voltage. Preferably, the insulating sleeve of the bifurcated coaxial cable is also bifurcated, but it extends only to just in front of the neutral electrode.

In the case of the bifurcated coaxial cable, the neutral electrode is preferably an elongated metal sheet, bent slightly around the endoscope shaft and extending from one branch of the bifurcation to the other. The sheet can have projections at the four corners which are placed around the shields. Depending on the degree of placing around and also clamping, any desired fixing of the neutral electrode to the coaxial cable can be obtained.

The current density in the area of the operating zone is advantageously influenced if the neutral electrode terminates at a distance from the end of the shield.

According to a further advantageous embodiment, the neutral electrode comprises two partial electrodes extending in the direction of the loop away from the two arms of the bifurcation. Preferably, the partial electrodes do not extend quite as far from the shields as the loop. At the front and rear ends the sheets preferably have rounded portions.

As a result of the slide-like construction, the operator can reliably guide the endoscope by placing the slide-like sheet projections on the tissue to then be removed. As is known, the endoscope is operated in such a way that the cutting loop is moved forwards relative to the endoscope, made live and then slowly retracted, whereby the tissue is removed by the heating on the cutting loop.

As stated hereinbefore, the treatment electrode and neutral electrode are appropriately so shaped and posi-

tioned that the illumination, vision and washing operations are not impaired by the endoscope.

Advantageously, the leads are inductively connected to the high frequency generator, whereby advantageously, a capacitor for filtering out low frequency voltage portions is preferably provided in one lead. This, in advantageous manner avoids faradic effects in the muscular system of the patient.

A capacitor is appropriately connected in parallel to the output winding of the transmitter which with the inductor of the latter forms an oscillating circuit which is tuned in such a way that the attenuation in the oscillating circuit formed by the leads, treatment electrode and neutral electrode is minimal.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects of the present invention will be apparent from the following description and claims and are illustrated in the accompanying drawings which, by way of illustration show preferred embodiments of the present invention and the principles thereof and what are now considered to be the best modes contemplated for applying these principles. Other embodiments of the invention embodying the same or equivalent principles may be used and structural changes may be made if desired by those skilled in the art without departing from the invention and the scope of the appended claims.

In the drawings show:

FIG. 1 a schematic, greatly enlarged perspective view of the front end of an endoscope equipped with the electro-surgical device according to the invention.

FIG. 2 a perspective view of a further embodiment of the electro-surgical device according to the invention, without the endoscope surrounding the same.

FIG. 3 a further embodiment of the electro-surgical device according to the invention, once again without a surrounding endoscope.

FIG. 4 a schematic circuit diagram of the electro-surgical device according to the invention with a particularly suitable high frequency generator.

FIGS. 5 and 6 perspective views of two further advantageous embodiments

FIGS. 7 and 8 a perspective view and an axial section of a further advantageous embodiment.

FIG. 9 a schematic circuit diagram of an additional device for the device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to FIG. 1, an endoscope 13 is axial traversed in conventional manner by a fibre optical system 17, which is spaced relative to the sides of the endoscope 13, in such a way that washing liquid can pass through there (arrow 29) and there still remains space for the axial insertion of an electro-surgical treatment device.

According to the invention, this electro-surgical treatment device comprises a coaxial cable 19 with rigid metallic shield 14 and an inner conductor 16 axially inserted together with the fibre optical system 17. Inside the metallic shaft of the endoscope 13, the shield 14 is covered in not shown manner with an insulating sleeve 22, shown in the case of the constructions of FIGS. 2 and 3.

At the front, inner conductor 16 projects somewhat from the coaxial cable 19 and passes into the treatment electrode 12, which in general comprises a loop ensur-

ing free visibility for the operator via the fibre optical systems 17.

The opposite electrode for the cutting electrode 12 is formed by a neutral electrode 11 fixed in electrically conductive manner to shield 14 and which is curved somewhat about the endoscope shaft, having a rectangular, elongated form shown in FIG. 1. Inner conductor 16 and shield 14 are connected, as shown in FIG. 4 to the two poles of a high frequency generator 15 which are not at earth potential.

At the front end of the metal shaft of the endoscope 13 is fixed a plastic extension 18, which is rounded and extends in the manner shown in FIG. 1, so as not to impair insertion, for example into the urethra. As the plastic extension 18 is an insulating body, the large-area neutral electrode 11' can also be fitted to the inside. It is then appropriately connected with the associated pole of the high frequency generator via a separate insulated conductor 14' in the endoscope, inside of via the shield 14.

As a result of the construction according to the invention, a high frequency field is only formed between shield 14 and inner conductor 16, as well as between neutral electrode 11 and treatment electrode 12, as is shown schematically in FIG. 4 by capacitors C_L and C . Due to the current conduction through the tissue fluid and tissue itself, a true resistor R is also conceivable parallel to the capacitor between neutral electrode 11 and treatment electrode 12.

The supply to connect neutral electrode 11 and the treatment electrode 12 takes place by the inductive coupling of a high frequency voltage by means of a transformer 25, whose input voltage is regulatable by a variable tap 30. Due to the inductive coupling, the output lines 14 and 16 are galvanically isolated from earth potential.

A capacitor 26 connected in lead 16 is used for filtering out the low frequency current and therefore avoids faradic effects in the muscular system of the patient. A capacitor 28 connected in parallel to the output winding 27 of transformer 25 and behind capacitor 26 forms with the output winding an oscillating circuit tuned in such a way that the attenuation in the oscillating circuit formed from C_L , C and R as well as the inductors of lines 14, 16 is minimal.

As a result of the construction according to the invention, the leakage currents only flow between lines 14, 16 and therefore do not reach the metal shaft of endoscope 13. Thus, larger current densities such as are necessary for tissue separation or coagulation only occur outside the endoscope in the operating area.

Therefore, the danger of heating outside the desired area, as well as burns to the operator is reliably avoided.

FIG. 2 shows a particularly advantageous embodiment of the electro-surgical device according to the invention in which both the inner conductor 16 and the shield 14 have a bifurcation 20. In the same way, the insulating sleeve drawn over the shield 14 is bifurcated. The production of such a bifurcation is advantageously obtained by a welded joint at point 31 indicated by a line.

As a result of the bifurcation shown in FIG. 2, a cutting loop 12 can be arranged in the shown manner between the two inner conductors 16 emanating at the end. If the treatment electrode is to be used for coagulation, a coagulation sparking ball 21 can be provided on loop 12.

The construction of FIG. 2 is particularly well suited to the arrangement of a relatively large-area neutral electrode 11 which appropriately extends between the shields 14 of the two branches of the bifurcation 20, being slightly bent about the endoscope shaft. At the end, the neutral electrode 11 has projections 23 which are securely placed around the shields 14 for securing neutral electrodes 11 and for supplying the same with voltage. The metal sheeting forming the neutral electrode simultaneously constructionally reinforces the bifurcation 20, so that the guidance of the treatment electrode 12 by the operator is aided. As is known, the axial movement of the electro-surgical device in the direction of the double arrow f takes place by operating a pistol-like handle on endoscope 13, not shown in the drawing.

A further advantageous embodiment is shown in FIG. 3 where the neutral electrode is broken up into two partial electrodes 11a, 11b, which in the represented manner are soldered or welded to the shields 14 in such a way that the partial electrodes extend in the same direction as cutting loop 12. Rounded portions 24 are provided at both ends. The partial electrodes 11a, 11b applied to the shields 14 in this way thus additionally form slide-like support, by means of which the electro-surgical device can be placed on the tissue to be removed. This not only ensures a reliable guidance of the device but also ensures that the tissue is removed to the predetermined depth. The electrical advantages of limiting current conduction to the operating area are completely maintained.

FIG. 5 shows a further advantageous embodiment, whereby only the front part of the electro-surgical device without the endoscope is shown. In this embodiment, two insulated cables with inner conductors 14, 16 are passed from high frequency generator 15 through the endoscope. At the front end are successively arranged the cutting loop 12 and the neutral electrode 11 constructed as a steel band. The cutting loop 12 is electrically conductively connected with the inner conductor 16, but at the other end is only fixed to the insulation surrounding the conductor 14. Conversely, the steel band 11, whose shape is similar to the cutting loop 12, is connected in electrically conductive and mechanically secure manner with the inner conductor 14, whilst the opposite end is mechanically secured to the insulation of the inner conductor 16. Since, according to the invention, the steel band 11 has the same radius as the wire loop, on retracting the loop 12 in the direction of arrow F , the band does not form an obstacle to the tissue portions removed by the loop. The neutral electrode 11 in the form of the steel band rests on the tissue in large-area form, so that good electrical contact is ensured.

FIG. 6 shows an embodiment which is substantially the same as FIG. 5, whereby however, a bifurcated coaxial cable, similar to FIGS. 2 and 3 is used. The wire loop 12 is once again fixed to the inner conductors 16, whilst the neutral conductor 11 in band form is mechanically secured to extensions 14' electrically connected with the shield 14.

In the embodiment according to FIGS. 7 and 8, the front portion of endoscope 13 itself or a coaxial connection attached thereto at the front is constructed as the neutral electrode 11. To this end, the front portion is electrically insulated relative to the rear portion or the front-fitted connection from endoscope 13 by an immediately inserted insulating ring 36. The cutting loop 12 can at the front be passed out of the neutral electrode

11 in one of the above-described manners. In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of endoscope 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator 15 not shown in FIGS. 7 and 8.

It is also important in the case of the embodiments of FIGS. 7 and 8 that the cutting loop extends radially up to an insulating ring 35 mounted at the front on the neutral electrode 11 and can be retracted up to this. In this way, the front edge of the endoscope shaft, namely the front edge of the insulating ring 35 serves as a support for the cutting loop 12, so that the material is reliably removed therefrom. Therefore, as shown the insulating ring 35 must be rounded at the front.

Preferably, the insulating rings 35, 36 have axial attachments 37 with a reduced external diameter, by means of which a mechanically secure fixing to the metal tubes is ensured.

FIG. 9 shows an additional device 32, by means of which a conventional high frequency surgical apparatus 15' with an earthed output terminal can be made usable for the purposes of the invention. The additional device 32 connected to the high frequency apparatus 15' has at the inlet a transformer 33 with parallel-connected capacitor 34 for tuning to the resonant frequency of the output circuit of the high frequency apparatus 15'. The output winding of transformer 33 is preferably regulatable by means of a loop arm 38 in such a way that the inductive output transformer 25 can receive voltages of varying sizes.

Via a capacitor 26, the output winding of transformer 25 is applied to the two output terminals of the additional device 32, where the leads 14, 16 can be applied.

In this way the high frequency apparatus 15' acquires an output with fluctuating potential, as is necessary for the connection of the electro-surgical device according to the invention.

The invention is not limited to the embodiments described and represented hereinbefore and various modifications can be made thereto without passing beyond the scope of the invention.

What is claimed is:

1. In combination: an endoscope having an endoscope body of substantially tubular shape, and an electro-surgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an-insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.

2. The combination of claim 1, wherein said insulated cable means and said means for connecting said neutral electrode to said other pole comprise coaxial cable means with shielding means forming one of said connecting means and being insulated relative to said endoscope body.

3. The combination according to claim 2, wherein said shielding means is constructed as a rigid sleeve in which said treatment electrode is adapted to be moved back and forth relative to said endoscope body through said coaxial cable means.

4. The combination according to claim 2, wherein said neutral electrode is fixed directly to said shielding means of said coaxial cable means.

5. The combination according to claim 4, wherein the neutral electrode is constructed as an elongated metal sheet slightly bent within said endoscope body and extending over said coaxial cable means.

6. The combination according to claim 2, comprising an insulating sleeve surrounding said coaxial cable means.

7. The combination according to claim 6, wherein said insulating sleeve is bifurcated and extends approximately to said neutral electrode.

8. The combination according to claim 7, wherein said neutral electrode is an elongated metal sheet slightly bent within said endoscope body and extending from one branch of said bifurcated insulating sleeve to the other.

9. The combination according to claim 8, wherein said sheet has projections at its four corners, two each of which are placed around the respective branches of said bifurcated sleeve.

10. The combination according to claim 2, wherein said neutral electrode terminates at a distance from said shielding means.

11. The combination according to claim 1, wherein said neutral electrode is secured to and insulated from said endoscope body on the inside of said insulating projection.

12. The combination according to claim 1, wherein said means for connecting said neutral electrode to said high-frequency generator is an insulated conductor secured in said endoscope body.

13. The combination according to claim 2, wherein said coaxial cable means has a bifurcation at that end of the endoscope body adjacent said projection, two inner conductors emanating from said bifurcation, and a loop interconnecting said two inner conductors and forming said treatment electrode.

14. The combination according to claim 1, wherein a coagulation sparking ball is fitted to said treatment electrode.

15. The combination according to claim 1, comprising a high-frequency generator, and wherein said cable means and said connecting means are inductively coupled to said high-frequency generator.

16. The combination according to claim 15, wherein a capacitor is connected in one of said cable means and said connecting means for filtering out low-frequency voltage.

17. The combination according to claim 15, wherein said generator comprises a transformer with an output winding having an inductor, a capacitor being connected parallel to said output winding and forming an oscillating circuit with said inductor, said circuit being tuned such that the attenuation in said circuit formed by said cable means, said connecting means, treatment electrode and neutral electrode is minimal.

18. The combination according to claim 15, comprising means for potential isolation connected between said high-frequency generator and said cable means and said connecting means respectively.

19. The combination according to claim 18, wherein said potential isolation means comprises a transformer, a capacitor connected parallel to said transformer, said high-frequency generator having an output circuit, said

transformer and said output circuit being tuned in resonance.

20. The combination according to claim 19, comprising an inductive transformer connected to said transformer, said cable means and said connecting means being connected to said inductive transformer.

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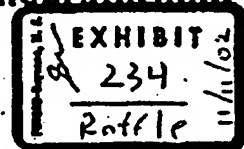
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Über ein Instrument zur leckstromfreien transurethralen Resektion

Von E. ELSÄSSER und E. ROOS

Krankenhaus der Barmherzigen Brüder, Urologische Abteilung, München, Chefarzt: Priv.-Doz. E. Elsässer / Dr. W. Schneider



Nach transurethralen elektrokirurgischen Operationen — meist Resektionen an Prostata oder Harnblase — treten in nicht zu unterschätzender Häufigkeit Harnröhreninkrustationen auf, die mit größter Wahrscheinlichkeit als die Folge von Stromverletzungen der Harnröhre angesehen werden müssen (ELSÄSSER, ROOS, SCHNEIDT).

Bei allen chirurgischen Eingriffen mit hochfrequentem Wechselstrom wird der Organismus des Kranken Teil eines Stromkreises: Der vom Generator gele-

terte Hochfrequenzstrom tritt an der punktförmigen Schneidelektrode in den Organismus ein und fließt auf im einzelnen unbekannten Wegen zu der großflächigen, inaktiven, innerhalb des HF-Generators geerdeten Neutralelektrode und damit zum Erdpotential (Bild 1).

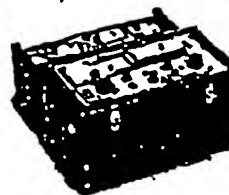
Unmittelbar unter der punktförmigen Aktivelektrode tritt der mit hoher Dichte eintretende Strom auf den hohen elektrischen Widerstand des Gewebes. Nach dem JOULEschen Gesetz Wärme =

Stromstärke² X Widerstand X Zeit entwickeln sich im Gewebe unter der Aktivelektrode so hohe Temperaturen, daß es durch Verdampfung von Gewebssubstanz zur Sprengung der Gewebestruktur und damit zur beabsichtigten Gewebedurchtrennung kommt. Da sich der Strom in der Regel sofort im Gewebe ausbreitet, nimmt er sehr rasch an Dichte ab und wird daher auf seinem weiteren Weg durch den Organismus zur Neutralelektrode erscheinungslos vertragen.

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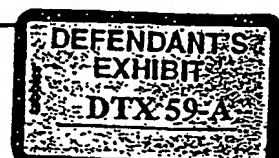


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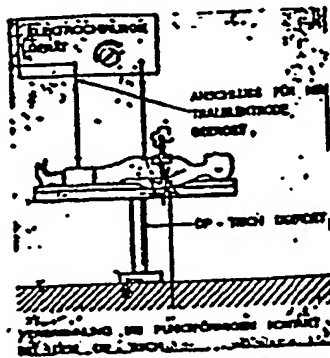
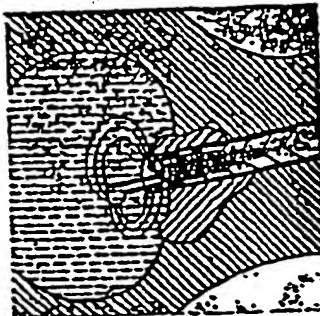


Bild 1: Stromverteilung bei Elektrochirurgie mit herkömmlicher geerdeter Neutral-Elektrode. Der Hochfrequenzstrom fließt dabei immer von der Arbeits-Elektrode auf dem Weg des geringsten Widerstandes zur Erde.

Entsprechend den elektrophysikalischen Gesetzen schlägt der Strom stets den Weg des geringsten Widerstandes zum Potentialausgleich ein. In der Regel wird ihm dieser Weg in Form der Neutral-Elektrode angeboten (Bild 1).

Kommt der Patient aber mit anderen geerdeten Metallteilen — etwa des Operationstisches — in Berührung, so kann der Strom auch dort zur Erde abfließen, und dies um so eher, wenn derartige Berührungspunkte dem Operationsgebiet sehr nahe gelegen sind oder wenn die Neutral-Elektrode durch unzureichende Fixierung dem Stromübergang einen höheren Widerstand entgegensetzt. Sind derartige Kontaktstellen mit geerdeten Leitern nur kleinflächig, so wird hier die Stromdichte enorm sehr hoch und es kann zu Verbrennungen kommen (Bild 2).

Bild 2: Strombelastung der Harnröhre bei herkömmlicher TUR durch Leckströme. Jeder dem kapazitiven Leckstrom fließt der Strom durch von der Schneidechlinge auf die in der Spülwasser-Mischungsgeräten Teile des Resektoskops.



Diese prinzipielle Gefahr von unbeabsichtigten Stromverletzungen des Gewebes abseits vom Operationsgebiet ist speziell bei urologischen Eingriffen aus dreierlei Gründen besonders hoch:

1. Für die Schnitte und Koagulationen unter Wasser werden besonders hohe Stromapplikationen benötigt

2. Die üblichen Resektoskope, die aus stromführenden (Schneidechlinge) und nichtstromführenden Metallteilen zusammengesetzt sind, stellen Kondensatoren dar, die einen kapazitiven Übergang des Hochfrequenzstromes auch auf die von den stromführenden Elementen kollierten Metallteile zulassen.

ELSSNER, ROOS und SCHMIEDT wiesen 1974 darauf hin, daß etwa 20% der auf die Schneidechlinge applizierten Hochfrequenzleistung kapazitiv als sogenannter „Leckstrom“ an den Resektoskopen verlorengehen.

Oberfläche eine inaktive Elektrode darstellt. Wenn sich der Stromübertritt jedoch aus irgendwelchen Gründen (vorübergehende Harnstranstrücker, Lücke im kollierenden Gleitringkette) bevorzugt — oder gar ausschließlich — an einer kleinen, circumskripten Stelle ereignet, wird die an dieser Stelle zu hohe Stromdichte zu elektrothermischer Schädigung des Gewebes führen. Aufgrund der besonderen anatomischen Gegebenheiten beim Mann — die meisten urologischen Pathologien sind ja Männer — muß außerdem die Summe aller an die Harnröhre abgegebenen Leckströme, bevor sie sich im kleinen Becken ausbreiten können, die Penetration passieren, so daß die Harnröhre im Bereich dieses Engpasses zwangsläufig einer besonders hohen Strombelastung ausgesetzt sein muß, die unter Umständen individuell nicht mehr toleriert wird.

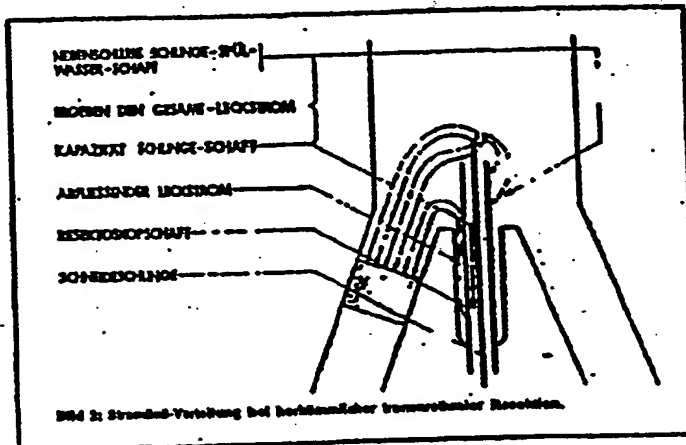


Bild 3: Stromverteilung bei herkömmlicher transurethraler Resektion.

Neuere und weitestgehende Untersuchungen am Phantom (Roos) haben ergeben, daß zusätzlich — durch Nebenschluß über das Spülwasser — Strom von der Schneidechlinge auf die von Spülwasser umflossenen Resektoskopteile (Schalt und Optik) übergehen kann. Der Resektoskopenstrom wird also sowohl kapazitiv wie über das Spülwasser erheblich aufgeladen (Bilder 2, 3 und 4).

3. Die Summe der Leckströme fließt über das dem Schalt anliegende Harnröhren- und Gewebe zur Neutral-Elektrode, was in der Regel unbemerkt und ohne nachteilige Folgen geschieht, weil der Resektoskopenstrom mit seiner großen

Um die Harnröhre vor dieser hohen Strombelastung und möglicher elektrothermischer Schädigung zu schützen, wurden in letzter Zeit Resektoskope gebaut, deren Schalt entweder ganz aus nichtleitendem Material (Teflon) besteht oder durch einen Überzug mit einem Teflonschlauch kolliert wird.

Aber auch solche Resektoskope sind in ihrer Anwendung nicht risikolos: Der nichtleitende Schalt verhindert zwar den Übertritt der Leckströme vom Resektoskopenstrom auf die Harnröhre, nicht aber die kapazitive Aufladung der im Inneren des Schalters gelegenen Metallteile. Da der Potentialausgleich über

Harnröhre und Neutralelektrode durch die Isolierung verhindert wird, sucht sich der Leckstrom einen anderen Weg zur Erde. Dieser Weg führt zwangsläufig über den Operateur, der durch seine nicht vermeidbare erhebliche Körperkapazität gegenüber dem Massepotential als Über einen nicht sehr hohen Widerstand geerdet angesehen werden muß. Unangenehme und zum Teil nicht ungefährliche Entladungserscheinungen im Gesicht des Operateurs sind die Folge (Bild 5). Auch an anderen Stellen, z. B. bei Berührung der Arme des Operateurs mit den geerdeten Armstützen des Operationsbettes, sind punktförmige Entladungen häufig.

Aber auch der Kranke kann Stromverletzungen erleiden: Wenn bei relativ langen Penals das Instrument bei eingeführt werden muß, kann es — wie in einem eigenen Fall — durch Kontakt der Glanz- und des Metallkörpers am Ende des Teilionschiffes zur zirkulären Verbrennung um den Meatus edianus herum kommen. Besonders gefährlich

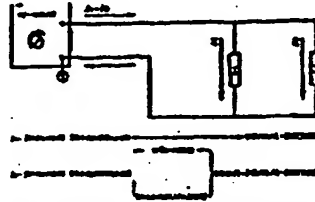


Bild 6: Ersatzschaltbild zu den Bildern 2 und 3.

Ist die Verwendung von Instrumenten mit teilionbeschichteter Metallschaft-Gekörte Defekte in der Teilionbeschichtung werden sofort zum Ort intensiven Stromübertrisses und thermoelektrischer Schädigung der Harnröhre.

Nachdem es offensichtlich nicht gelingt, Leckströme durch Isolierung einzudämmen, scheint es naheliegend, den umgekehrten Weg zu beschreiten: nämlich dem Hochfrequenzstrom einen so kurzen und widerstandsarmen Weg zum Potentialausgleich anzubieten, daß ablenkende Ströme oder Leckströme gar nicht auftreten.

Das geschieht

1. durch extreme räumliche Annäherung der inaktiven, großflächigen Neutralelektrode an die aktive Schneidelektrode, die einen Potentialausgleich zwischen beiden Elektroden auf engstem Raum, d. h. innerhalb des Operationsgebietes, also der Harnblase, ermöglicht, ohne daß andere Gewebebezirke in die Strombahn einbezogen werden. Der Strom fließt von der Schneideschlinge durch das anliegende, zu schneidende Gewebe und das Spülwasser unmittelbar zur Neutralelektrode.

2. durch den Anschluß beider Elektroden an einen Hochfrequenzgenerator mit erdschließbarem, schwebendem Ausgangskreis, sog. „floating output“.

Da in diesem erdschließbaren Ausgangskreis keine der Elektroden mit einem Erdpotential führt, besteht auch keine Spannung gegen das Erdpotential. Es kann sich somit kein Stromfluß vom Operationsfeld zur Erde ausbilden.

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Dieses Prinzip der Verwendung von bipolar ausgebildeten Elektroden in Verbindung mit einem ortschließenden, schwebenden Hochfrequenzstromkreis haben im Bereich der Gynäkologie HIRSCH und ROOS zur laparoskopischen Tubensterilisation und MELCHIOR für die Blutstillung durch bipolare Mikrokoagulation beschrieben.

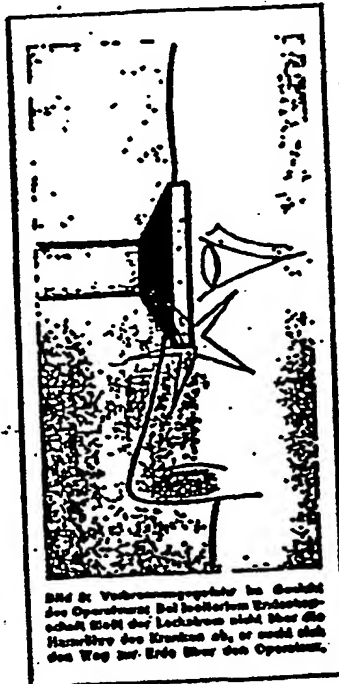
Am urologischen Resektoskop können Neutralelektrode und Aktualelektrode konstruktiv zu einer bipolaren Elektrode vereinigt werden, indem die Neutralelektrode — wie die Bilder 8 und 7 zeigen — als Metallplatte der Schneidanschlinge aufgesetzt wird.

Diese Konstruktion als bipolare Elektrode bietet operationstechnisch jedoch einige Schwierigkeiten: Durch die Anordnung des großflächigen Metallplättchens oberhalb der Schneidanschlinge werden offensichtlich die Stromungsverhältnisse gestört, so daß durch Blasenbildungen im Spülwasser die Sicht auf das Operationsfeld stark beeinträchtigt wird. Dieses Problem ist jedoch möglicherweise von einem erfahrenen Resektoskopchirurg zu lösen.

Eine zweite Möglichkeit, die Neutralelektrode als Metallring in das blasen-nahe Ende des Resektoskopgehäuses einzubauen (Bilder 8 und 9), hat sich dagegen operationstechnisch als problemlos erwiesen und gut bewährt.

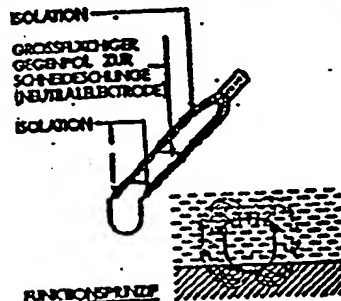
Schon Messungen am Phantom haben gezeigt, daß sowohl bei Verwendung der bipolaren wie der Fingerelektrode durch die neuerliche Stromführung sehr bessere elektrische Verhältnisse geschaffen werden. Der Resektoskop-schaft und das ihm anliegende Gewebe unterliegen keiner Belastung durch Leckströme, der Organismus ist — mit Ausnahme des kleinen Bereiches zwischen den beiden Elektroden — nicht in den Stromkreis eingeschaltet, abstrahlende Strahlung können nur in minimaler Stärke abgeleitet bzw. gemessen werden.

Wir haben ein herkömmliches Resektoskop mit einem derartigen, die Neutralelektrode tragenden Resektoskopgehäuse, wie ihn die Bilder 8 und 9 zeigen, versehen und die normale Schneid-



schlinge dieses Resektoskops wie auch die Neutralelektrode an ein von der Firma Martin*) zur Verfügung gestelltes, an die besonderen elektrischen Verhältnisse

Bild 9: Bipolare Elektrodenanordnung zum Schneiden bei Stromströmung. Beachtung: Der Strom fließt von der Schneidanschlinge durch zu der neben schließenden Neutralelektrode.



nasse angepaßtes HF-Chirurgiegerät mit „floating output“ angeschlossen.

Mit diesem, von uns selbst derart modifizierten Instrument (Bilder 8 und 9) haben wir bis jetzt insgesamt 27 Elektroresektionen der Prostata und fünf der Harnblase komplikationslos ausgeführt. Die Schneidfähigkeit der Schlinge war durch die neue Stromführung in keiner Weise beeinträchtigt. Es lassen sich mindestens ebenso gut wie mit den herkömmlichen Instrumenten mühelos glatte, schonende Schnitte ausführen. Dasselbe gilt für die Blutstillung, die mit der Koagulationselektrode ausgezeichnet gelingt.

Zur Prüfung der neuen elektrischen Verhältnisse haben wir bei fünf der insgesamt 32 Operationen elektrische Messungen durchgeführt. Die Anordnung der Meßinstrumente und die Meß-Streum sind in Bild 10 wiedergegeben.

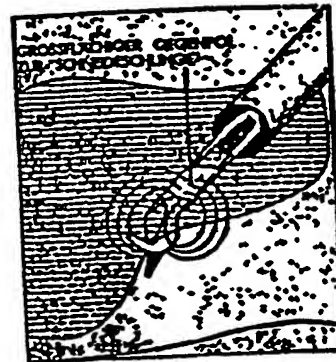


Bild 10: Auf einem Diagramm dargestelltes elektrisches Spannungsfeld bei Unterbrechung mit einer bipolaren Schneidanschlinge.

h = Ableitstrom vom Resektoskop zu einer am Oberkörper fixierten Neutralelektrode (bei richtigem Schluß fließt dieser Ableit- oder Leckstrom über die Handfläche zur Neutralelektrode zurück).

U = Elektrische Spannung zwischen Resektoskop und der Neutralelektrode.

* Firma Gerdner Martin, D-200 Tübingen

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- I_2 = Ableitstrom vom Resektoskop zur Erde (Ursache für Verbräunungen im Gesicht des Operateurs).
- U_2 = Elektrische Spannung zwischen Resektoskop und Erde.

- I_3 = Ableitstrom vom Patienten zur Erde (Ursache von Verbrennungen des Patienten bei kleinflächigen Kontakten mit erdpotenzialführenden, leitenden Op-Tisch-Teilen).
- U_3 = Elektrische Spannung zwischen Patient und Erde.

Als Meßinstrumente wurden verwendet:

Strommesser: Neuberger-Milliamperemeter mit Thermokreuz, Meßbereiche 0–150 mA u. 0–600 mA

Spannungsmesser: Kathodenstrahl-Oszillograph von Advance Electronics, Type OS 3000

Bei jedem zu Operierenden wurden die ersten Schritte mit einem herkömmlichen Resektoskop mit Teflonisolierung ausgeführt und dabei die während des Schneidvorganges auftretenden Leckströme und Spannungen gemessen. Abgeleitet wurde von den operativen Metallteilen des Instrumentes.

Nach Erfassung der Meßdaten wurde das Instrument gewechselt und die

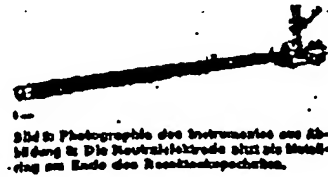


Abb 3: Photographie des Instrumentes aus Abbildung 2. Die Neutralisierede steht als Metallring am Ende des Resektoskopgehäuses.

Operation mit dem neuen, von uns modifizierten Resektoskop mit bipolarer Stromapplikation und erdschluttfähigem HF-Generator mit „floating output“ durchgeführt.

An gleichen Patienten wurden nacheinander unter den gleichen Bedingungen, bei unveränderter Lagerung die gleichen Messungen während des Schneidvorganges vorgenommen.

Die Tabelle zeigt das Mittel aus den gewonnenen Meßdaten, in der oberen Zeile bei herkömmlicher Technik, in der unteren Zeile mit dem neuen Instrument.

Der bei konventioneller Technik gemessene Leckstrom ist mit 150 mA so groß,

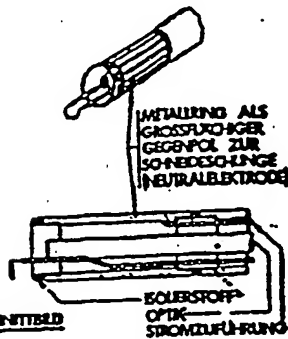
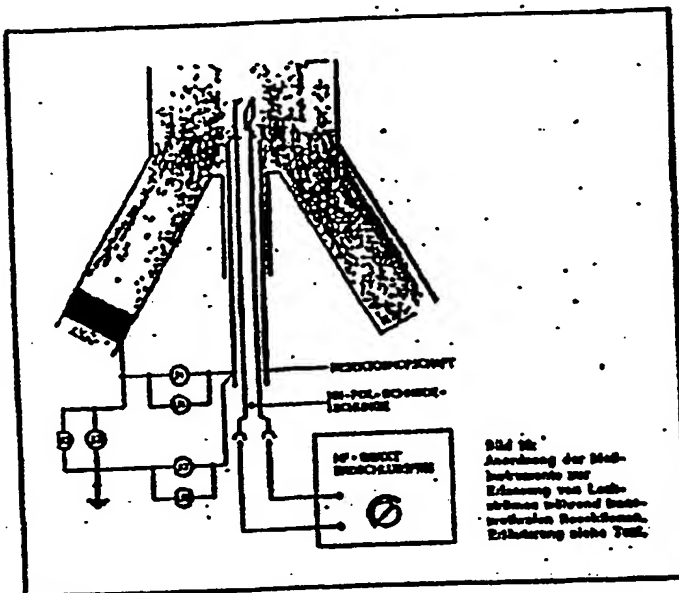


Abb 2: Elektrische Elektrodenanordnung zur Vermeidung von Leckströmen. Die Neutralisierede ist als Metallring am Ende des Resektoskopgehäuses angebracht.

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	<p>3 Flexible Anpassungsfähig- keit an Stoma-Öffnung durch vorgestanzte Öffnungsringe.</p>	

Tabelle: Meßdaten, Schaltung siehe Bild 10

Operativtechnik	I_1	U_1	I_2	U_2	I_3	U_3
konventionell, mit geerdeter Neu- tralelektrode	130 mA	300 V	— kurzgeschlossen — beide geerdet		entfällt, direkt kurzgeschlossen	
neue bi-polare Technik	15 mA	20 V	15 mA	20 V	< 5 mA	< 10 V



daß an kleinstmöglichen Kontaktstellen mit geerdeten Leitern auf jeden Fall mit Verbrennungen gerechnet werden muß, gleichgültig wo dieser Kontakt entsteht: Im Bereich der Harnblase oder der Haut des Kranken oder der Haut des Operateurs.

Die Meßwerte bei Anwendung der neuen bipolaren Technik liegen unterhalb des kritischen Bereiches, und es lassen sich mit großer Wahrscheinlichkeit durch konstruktive Verbesserungen am Resektoskop und am Zuleitungskabel noch weiter reduzieren.

Zusammenfassung

Es wird über ein Resektoskop mit neuartiger Anordnung der Elektroden berichtet, das mit einem hochfrequenten Hochfrequenzstromkreis arbeitet. Dieser

wurden damit 52 komplikationslose Resektionen ausgeführt. Der Hochfrequenzstrom, der von einem erschütterten Hochfrequenzgenerator mit schwachem Ausgangsstrom geliefert wird, fließt von der aktiven Schneidelektrode durch das zu schneidende Gewebe und das Spülwasser direkt zu der ringförmigen, am proximalen Ende des Resektoskopes angebrachten Neutralelektrode. Der Stromfluß im Organismus bleibt auf das kleine Operationsgebiet innerhalb der Blase beschränkt. Da die Zuleitungen zu beiden Elektroden keine Spannung gegenüber dem Massepotential (Erdepotential) aufweisen, kann sich auch kein Stromfluß vom Operationsfeld zur Erde ausbilden. Entsprechend können bei der neuen Methode — im Gegensatz zu den herkömmlichen — keine nennenswerten

Leckströme gemessen werden, die als Ursache von Stromverletzungen am Harntrakt oder Haut des Kranken in Frage kommen.

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- [3] MELCHOR, H. Bipolare Mikrospektroskop. Verb. Der Deutsche Ges. Urol. 28. Tg. 1973 Aachen, Springer Verlag Berlin - Heidelberg 1974, p. 345-346

Keywords

Leckstromfreie transurethrale Resektion — neues Instrument
Transurethral resection without leakage of current — new instrument
Résection transurétrale sans fuite de courant nouveau appareil
Resección transuretral sin fuga de corriente — un nuevo instrumento

Anschritt der Verfasser: Priv.-Doz. Dr. E. Elkeser, Krankenhaus der Barmherzigen Brüder, Urologische Abteilung, Rembrandtstraße 63, D-8000 München 70.

E. Roos, Ing. VDL, Fa. Gebr. Merz, D-7200 Tuttlingen.

Medizinal-Markt / Acta Medicotechnica

Unsere nächste Ausgabe hat „Technische Mittel in der Krankenpflege“ zum Fachthema. Außerdem berichtet Prof. Dr. Max Anker, Institut für Biomedizinische Technik der Universität Zürich und der ETHZ, über neue diagnostische Verfahren sowie über Geräte, die im seinem Institut entwickelt wurden.

Über ein Instrument zur leckstromfreien transurethralen Resektion

Von E. ELSÄSSER und E. ROOS

Krankenhaus der Barmherzigen Brüder, Urologische Abteilung, München, Chefärzte: Priv.-Doz. E. Elsässer / Dr. W. Schneider

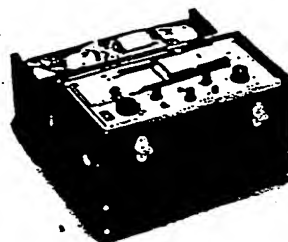
Nach transurethralen elektrochirurgischen Operationen — meist Resektionen an Prostata oder Harnblase — treten in nicht zu unterschätzender Häufigkeit Harnröhrenstrikturen auf, die mit größter Wahrscheinlichkeit als die Folge von Stromverletzungen der Harnröhre angesehen werden müssen (ELSÄSSER, ROOS, SCHMIEDT).

Bei allen chirurgischen Eingriffen mit hochfrequentem Wechselstrom wird der Organismus des Kranken Teil eines Stromkreises: Der vom Generator gelieferte Hochfrequenzstrom tritt an der punktförmigen Schneideelektrode in den Organismus ein und fließt auf im einzelnen unbekannten Wegen zu der großflächigen, inaktiven, innerhalb des HF-Generators geerdeten Neutralelektrode und damit zum Erdpotential (Bild 1).

Unmittelbar unter der punktförmigen Aktivelektrode trifft der mit hoher Dichte eintretende Strom auf den hohen elektrischen Widerstand des Gewebes. Nach dem JOULE'schen Gesetz: Wärme =

$\text{Stromstärke}^2 \times \text{Widerstand} \times \text{Zeit}$ entwickeln sich im Gewebe unter der Aktivelektrode so hohe Temperaturen, daß es durch Verdampfung von Gewebsflüssigkeit zur Sprengung der Gewebestruktur und damit zur beabsichtigten Gewebsdurchtrennung kommt. Da sich der Strom in der Regel sofort im Gewebe ausbreitet, nimmt er sehr rasch an Dichte ab und wird daher auf seinem weiteren Weg durch den Organismus zur Neutralelektrode erscheinungsfrei vertragen.

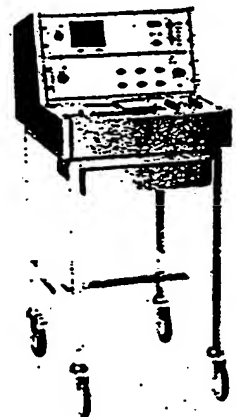
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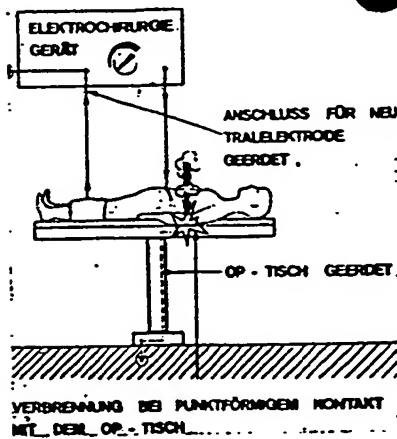
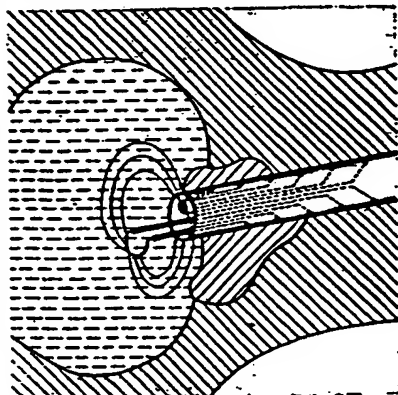


Bild 1: Stromkreis bei Elektrophysik mit herkömmlicher geerdeter Neutralelektrode. Der Hochfrequenzstrom fließt dabei immer von der Aktivelektrode auf dem Weg des geringsten Widerstandes zur Erde.

Entsprechend den elektrophysikalischen Gesetzen schlägt der Strom stets den Weg des geringsten Widerstandes zum Potentialausgleich ein. In der Regel wird ihm dieser Weg in Form der Neutralelektrode angeboten (Bild 1).

Kommt der Patient aber mit anderen geerdeten Metallteilen — etwa des Operationstisches — in Berührung, so kann der Strom auch dort zur Erde abfließen, und dies um so eher, wenn derartige Berührungspunkte dem Operationsgebiet sehr nahe gelegen sind oder wenn die Neutralelektrode durch unsachgemäße Fixierung dem Stromübergang einen höheren Widerstand entgegensetzt. Sind derartige Kontaktstellen mit geerdeten Leitern nur kleinflächig, so wird hier die Stromdichte erneut sehr hoch und es kann zu Verbrennungen kommen (Bild 1).

Bild 3: Strombelastung der Harnröhre bei herkömmlicher TUR durch Leckströme: Außer dem kapazitiven Leckstrom fließt der Strom direkt von der Schneidschlinge auf die in das Spülwasser hineinragenden Teile des Resektoskops.



Diese prinzipielle Gefahr von unbeabsichtigten Stromverletzungen des Gewebes abseits vom Operationsgebiet ist speziell bei urologischen Eingriffen aus dreierlei Gründen besonders hoch:

1. Für die Schnitte und Koagulationen unter Wasser werden besonders hohe Stromapplikationen benötigt.
2. Die üblichen Resektoskope, die aus stromführenden (Schneideschlinge) und nichtstromführenden Metallteilen zusammengesetzt sind, stellen Kondensatoren dar, die einen kapazitiven Übergang des Hochfrequenzstromes auch auf die von den stromführenden Elementen isolierten Metallteile zulassen.

ELSÄSSER, ROOS und SCHMIEDT wiesen 1974 darauf hin, daß etwa 20% der auf die Schneidschlinge applizierten Hochfrequenzleistung kapazitiv als sogenannter „Leckstrom“ an den Resektoskopschaft verlorengehen.

Oberfläche eine inaktive Elektrode darstellt. Wenn sich der Stromübertritt jedoch aus irgendwelchen Gründen (vorbestehende Hamröhrenstriktur, Lücke im isolierenden Gleitmittelfilm) bevorzugt — oder gar ausschließlich — an einer kleinen, circumskripten Schaftstelle ereignet, wird die an dieser Stelle zu hohe Stromdichte zu elektrothermischer Schädigung des Gewebes führen. Aufgrund der besonderen anatomischen Gegebenheiten beim Mann — die meisten urologischen Patienten sind ja Männer — muß außerdem die Summe aller an die Hamröhre abgegebenen Leckströme, bevor sie sich im kleinen Becken ausbreiten können, die Peniswurzel passieren, so daß die Hamröhre im Bereich dieses Engpasses zwangsläufig einer besonders hohen Strombelastung ausgesetzt sein muß, die unter Umständen individuell nicht mehr toleriert wird.

NEBENSCHLUß SCHLINGE-SPÜLWASSER-SCHAFT

ERGEBEN DEN GESAMT-LECKSTROM

KAPAZITÄT SCHLINGE-SCHAFT

ABFLIEßENDER LECKSTROM

RESEKTOSKOP-SCHAFT

SCHNEIDESCHLINGE

Bild 2: Stromfluß-Verteilung bei herkömmlicher transurethraler Resektion.

Neuere und weitergehende Untersuchungen am Phantom (Roos) haben ergeben, daß zusätzlich — durch Nebenschluß über das Spülwasser — Strom von der Schneidschlinge auf die von Spülwasser umfluteten Resektoskopteile (Schaft und Optik) übergehen kann. Der Resektoskopschaft wird also sowohl kapazitiv wie über das Spülwasser erheblich aufgeladen (Bilder 2, 3 und 4).

3. Die Summe der Leckströme fließt über das dem Schaft anliegende Hamröhrengewebe zur Neutralelektrode, was in der Regel unbemerkt und ohne nachteilige Folgen geschieht, weil der Resektoskopschaft mit seiner großen

Um die Hamröhre vor dieser hohen Strombelastung mit möglicher elektrothermischer Schädigung zu schützen, wurden in letzter Zeit Resektoskope gebaut, deren Schaft entweder ganz aus nichtleitendem Material (Teflon®) besteht oder durch einen Überzug mit einem Teflonschlauch isoliert wird.

Aber auch solche Resektoskope sind in ihrer Anwendung nicht risikolos: Der nichtleitende Schaft verhindert zwar den Übertritt der Leckströme vom Resektoskopschaft auf die Hamröhre, nicht aber die kapazitive Aufladung der im Inneren des Schafes gelegenen Metallteile. Da der Potentialausgleich über

Harnröhre und Neutralelektrode durch die Isolierung verhindert wird, sucht sich der Leckstrom einen anderen Weg zur Erde. Dieser Weg führt zwangsläufig über den Operateur, der durch seine nicht vermeidbare erhebliche Körperkapazität gegenüber dem Massepotential als über einen nicht sehr hohen Widerstand geerdet angesehen werden muß. Unangenehme und zum Teil nicht ungefährliche Entladungserscheinungen im Gesicht des Operateurs sind die Folge (Bild 5). Auch an anderen Stellen, z.B. bei Berührung der Arme des Operateurs mit den geerdeten Armstützen des Operationstisches, sind punktförmige Entladungen häufig.

Aber auch der Kranke kann Stromverletzungen erleiden: Wenn bei relativ langem Penis das Instrument tief eingeführt werden muß, kann es — wie in einem eigenen Fall — durch Kontakt der Glans mit den Metallteilen am Ende des Teflonschafftes zur zirkulären Verbrennung um den Meatus externus herum kommen. Besonders gefährlich

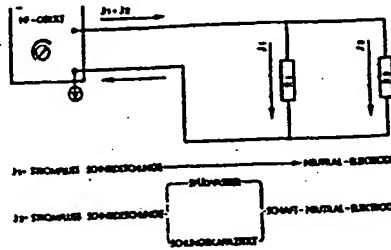


Bild 4: Ersatzschaltbild zu den Bildern 2 und 3.

ist die Verwendung von Instrumenten mit teflonbeschichtetem Metallschaft: Kleinste Defekte in der Teflonbeschichtung werden sofort zum Ort intensiven Stromübertrittes und thermoelektrischer Schädigung der Harnröhre.

Nachdem es offensichtlich nicht gelingt, Leckströme durch Isolierung einzudämmen, scheint es naheliegend, den umgekehrten Weg zu beschreiten: nämlich dem Hochfrequenzstrom einen so kurzen und widerstandsarmen Weg zum Potentialausgleich anzubieten, daß aberrierende Ströme oder Leckströme gar nicht auftreten.

Dies geschieht

1. durch extreme räumliche Annäherung der inaktiven, großflächigen Neutralelektrode an die aktive Schneidelektrode, die einen Potentialausgleich zwischen beiden Elektroden auf engstem Raum, d.h. innerhalb des Operationsgebietes, also der Harnblase, ermöglicht, ohne daß andere Gewebsbezirke in die Strombahn einbezogen werden. Der Strom fließt von der Schneideschlinge durch das anliegende, zu schneidende Gewebe und das Spülwasser unmittelbar zur Neutralelektrode.

2. durch den Anschluß beider Elektroden an einen Hochfrequenzgenerator mit erdschlußfreiem, schwebendem Ausgangskreis, sog. „floating output“.

Da in diesem erdschlußfreien Ausgangskreis keine der Elektrodenzuleitungen Erdpotential führt, besteht auch keine Spannung gegen das Erdpotential. Es kann sich somit kein Stromfluß vom Operationsfeld zur Erde ausbilden.

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Dieses Prinzip der Verwendung von bipolar ausgebildeten Elektroden in Verbindung mit einem erdschlußfreien, schwebenden Hochfrequenzstromkreis haben im Bereich der Gynäkologie HIRSCH und ROOS zur laparoskopischen Tubensterilisation und MELCHIOR für die Blutstillung durch bipolare Mikrokoagulation beschrieben.

Am urologischen Resektoskop können Neutralelektrode und Aktivelektrode konstruktiv zu einer bipolaren Elektrode vereinigt werden, indem die Neutralelektrode — wie die Bilder 6 und 7 zeigen — als Metallplatte der Schneideschlinge aufgesetzt wird.

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Eine zweite Möglichkeit, die Neutralelektrode als Metallring in das blasennahe Ende des Resektoskopschaftes einzubauen (Bilder 8 und 9), hat sich dagegen operationstechnisch als problemlos erwiesen und gut bewährt.

Schon Messungen am Phantom haben gezeigt, daß sowohl bei Verwendung der bipolaren wie der Ringelektrode durch die neuartige Stromführung sehr saubere elektrische Verhältnisse geschaffen werden. Der Resektoskopschaft und das ihm anliegende Gewebe unterliegen keiner Belastung durch Leckströme, der Organismus ist — mit Ausnahme des kleinen Bezirkes zwischen den beiden Elektroden — nicht in den Stromkreis eingeschaltet, aberrierende Ströme können nur in minimaler Stärke abgeleitet bzw. gemessen werden.

Wir haben ein herkömmliches Resektoskop mit einem derartigen, die Neutralelektrode tragenden Resektoskopschaft, wie ihn die Bilder 8 und 9 zeigen, versehen und die normale Schneide-

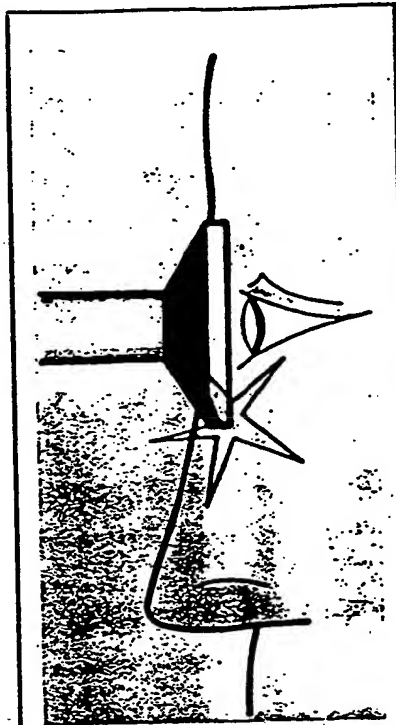
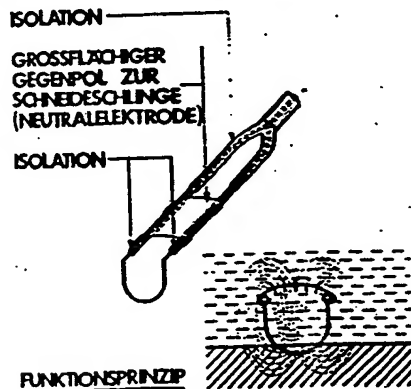


Bild 5: Verbrennungsgefahr im Gesicht des Operateurs: Bei isoliertem Endoskop-schaft fließt der Leckstrom nicht über die Harnröhre des Kranken ab, er sucht sich den Weg zur Erde über den Operateur.

schlinge dieses Resektoskopes wie auch die Neutralelektrode an ein von der Firma Martin*) zur Verfügung gestelltes, an die besonderen elektrischen Verhält-

Bild 6: Bipolare Elektroden-Anordnung zum Schneiden bei transurethraler Resektion: Der Strom fließt von der Schneideschlinge direkt zu der nahen schiffelförmigen Neutralelektrode.



nisse angepaßtes HF-Chirurgiegerät mit „floating output“ angeschlossen.

Mit diesem, von uns selbst derart modifizierten Instrument (Bilder 8 und 9) haben wir bis jetzt insgesamt 27 Elektresektionen der Prostata und fünf der Harnblase komplikationslos ausgeführt. Die Schneidefähigkeit der Schlinge war durch die neue Stromführung in keiner Weise beeinträchtigt: Es lassen sich mindestens ebenso gut wie mit den herkömmlichen Instrumenten mühelos glatte, schorffreie Schnitte ausführen.

Dasselbe gilt für die Blutstillung, die mit der Koagulationselektrode ausgezeichnet gelingt.

Zur Prüfung der neuen elektrischen Verhältnisse haben wir bei fünf der insgesamt 32 Operierten elektrische Messungen durchgeführt. Die Anordnung der Meßinstrumente und die Meß-Strecken sind in Bild 10 wiedergegeben:

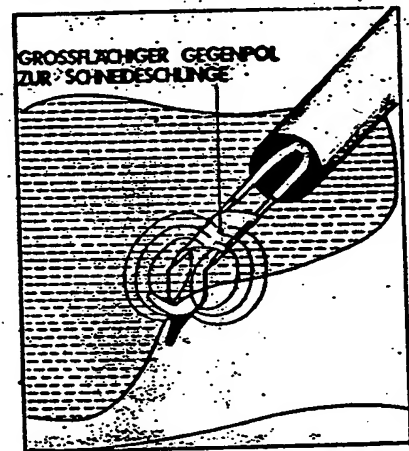


Bild 7: Auf engen Raum eingeschränktes elektrisches Spannungsfeld bei Unterwasserschneide mit einer bipolaren Schneideschlinge.

I_1 = Ableitstrom vom Resektoskop zu einer am Oberschenkel fixierten Neutralelektrode (bei nichtisoliertem Schaft fließt dieser Ableit- oder Leckstrom über die Harnröhre zur Neutralelektrode zurück).

U_1 = Elektrische Spannung zwischen Resektoskop und der Neutralelektrode.

*) Firma Gebrüder MARTIN, D-7200 Tuttlingen.

Asepsis im OP

Lautenschläger

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I_2 = Ableitstrom vom Resektoskop zur Erde (Ursache häufiger Verbrennungen im Gesicht des Operateurs).

U_2 = Elektrische Spannung zwischen Resektoskop und Erde.

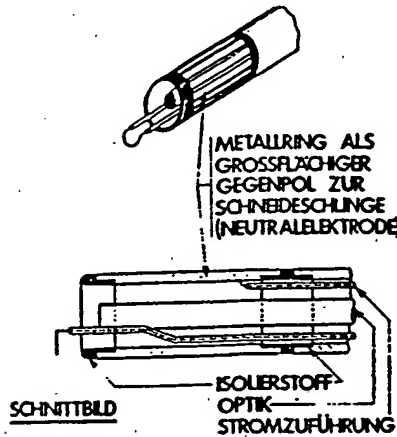


Bild 8: Bipolare Elektrodenanordnung zur transurethralen Resektion: Die Neutralelektrode ist als Metallring am Ende des Resektoskopschaftes angebracht.

I_3 = Ableitstrom vom Patienten zur Erde (Ursache von Verbrennungen des Patienten bei kleinflächigen Kontakten mit erdpotentialführenden, leitenden Op-Tisch-Teilen).

U_3 = Elektrische Spannung zwischen Patient und Erde.

Als Meßinstrumente wurden verwendet:
Strommesser: Neuberger-Milliampere-meter mit Thermokreuz, Meßbereiche 0—150 mA u. 0—600 mA

Spannungsmesser: Kathodenstrahl-Oszillograph von Advance Electronics, Type OS 3000

Bei jedem zu Operierenden wurden die ersten Schnitte mit einem herkömmlichen Resektoskop mit Teflonisolierung ausgeführt und dabei die während des Schneidevorganges auftretenden Leckströme und Spannungen gemessen. Abgeleitet wurde von den operateurnahen Metallteilen des Instrumentes.

Nach Erfassung der Meßdaten wurde das Instrument gewechselt und die



Bild 9: Photographie des Instrumentes aus Abbildung 8: Die Neutralelektrode sitzt als Metallring am Ende des Resektoskopschaftes.

Operation mit dem neuen, von uns modifizierten Resektoskop mit bipolarer Stromapplikation und erdschlußfreiem HF-Generator mit „floating output“ durchgeführt.

Am gleichen Patienten wurden nunmehr unter den gleichen Bedingungen, bei unveränderter Lagerung die gleichen Messungen während des Schneidevorganges vorgenommen.

Die Tabelle zeigt das Mittel aus den gewonnenen Meßdaten, in der oberen Zeile bei herkömmlicher Technik, in der unteren Zeile mit dem neuen Instrument.

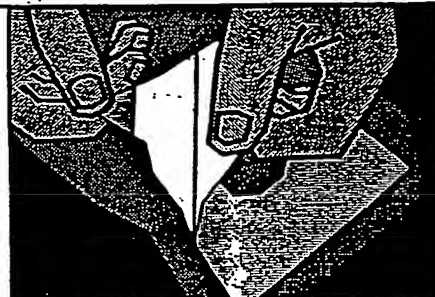
Der bei konventioneller Technik gemessene Leckstrom ist mit 150 mA so groß,

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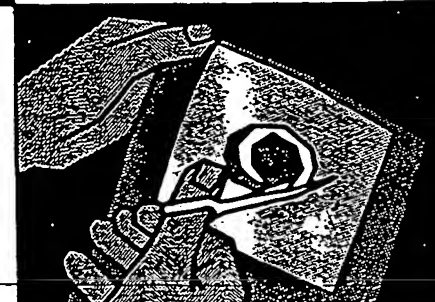
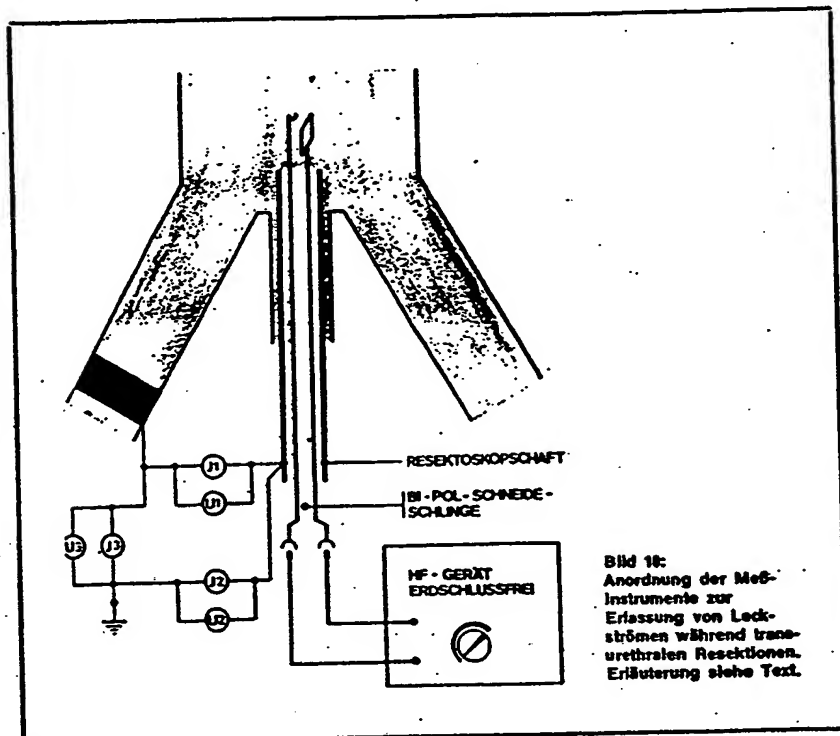


Tabelle: Meßdaten, Schaltung siehe Bild 10

Operationstechnik	I_1	U_1	I_2	U_2	I_3	U_3
konventionell, mit geerdeter Neu- tralelektrode	150 mA	300 V	— kurzgeschlossen — beide geerdet		entfällt, direkt kurzgeschlossen	
neue bi-polare Technik	15 mA	20 V	15 mA	20 V	< 5 mA	< 10 V



daß an kleinflächigen Kontaktstellen mit geerdeten Leitern auf jeden Fall mit Verbrennungen gerechnet werden muß, gleichgültig wo dieser Kontakt entsteht: Im Bereich der Harnröhre oder der Haut des Kranken oder der Haut des Operateurs.

Die Meßwerte bei Anwendung der neuen bipolaren Technik liegen unterhalb des kritischen Bereiches, und sie lassen sich mit großer Wahrscheinlichkeit durch konstruktive Verbesserungen am Resektoskop und am Zuleitungskabel noch weiter reduzieren.

Zusammenfassung

Es wird über ein Resektoskop mit neuartiger Anordnung der Elektroden berichtet, das mit einem leckstromfreien Hochfrequenzstromkreis arbeitet. Bisher

wurden damit 32 komplikationslose Resektionen ausgeführt.

Der Hochfrequenzstrom, der von einem erdschlußfreien Hochfrequenzgenerator mit schwebendem Ausgangskreis geliefert wird, fließt von der aktiven Schneideelektrode durch das zu schneidende Gewebe und das Spülwasser direkt zu der ringförmigen, am proximalen Ende des Resektoskopschaftes angebrachten Neutralelektrode. Der Stromfluß im Organismus bleibt auf das kleine Operationsgebiet innerhalb der Blase beschränkt. Da die Zuleitungen zu beiden Elektroden keine Spannung gegenüber dem Massepotential (Erdpotential) aufweisen, kann sich auch kein Stromfluß vom Operationsfeld zur Erde ausbilden. Entsprechend können bei der neuen Methode — im Gegensatz zu den herkömmlichen — keine nennenswerten

Leckströme gemessen werden, die als Ursache von Stromverletzungen an Harnröhre oder Haut des Kranken in Frage kommen.

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- [1] ELSASSER, E., ROOS, E., u. SCHMIEDT, E.: Leckstrom infolge kapazitiven Stromüberganges als Ursache von Harnröhrenstrikturen nach TUR. Verh. Ber. Deutsche Ges. Urol. 28. Tg. 1974 München. Springer Verlag Berlin — Heidelberg, 1975, p. 44—48.
- [2] HIRSCH, HA., und ROOS, E.: Laparoskopische Tubensterilisation mit einer neuen Bikoagulationszange. Geburtsh. u. Frauenheilk. 34, 340—344 (1974).
- [3] MELCHIOR, H.: Bipolare Mikrokoagulation. Verh. Ber. Deutsch. Ges. Urol. 25. Tg. 1973 Aachen. Springer Verlag Berlin — Heidelberg 1974, p. 144—145.

Keywords:

Leckstromfreie transurethrale Resektion — neues Instrument

Transurethral resection without leakage of current — new instrument

Résection transuretrale sans fuite de courant nouveau appareil

Resección transuretral sin fuga de corriente — un nuevo instrumento

Anschrift der Verfasser: Priv.-Doz. Dr. E. Elsässer, Krankenhaus der Barmherzigen Brüder, Urologische Abteilung, Romanstraße 93, D-8000 München 19.

E. Roos, Ing. VDI, Fa. Gebr. Martin, D-7200 Tuttlingen.

Medizinal-Markt / Acta Medico-technica

Unsere nächste Ausgabe hat „Technische Mittel in der Krankenpflege“ zum Fachthema. Außerdem berichtet Prof. Dr. Max Anliker, Institut für Biomedizinische Technik der Universität Zürich und der ETHZ, über neue diagnostische Verfahren sowie über Geräte, die an seinem Institut entwickelt wurden.

Translated title: An instrument for transurethral resection without leakage of current

German title: Über ein Instrument zur leckstromfreien transurethralen Resektion

Author: Elsässer, E.; Roos, E.

Author's affiliation: Krankenhaus der Barmherzigen Brüder, Urologische Abteilung [Brothers of Charity Hospital, Department of Urology], Munich

Source: *Medizinisch-Markt/Acta Medico-technica*, Vol. 24, No. 4, 1976. Pages 129-134.

Urethral strictures, which should in all probability be regarded as the result of electrical injury to the urethra, occur not infrequently after transurethral electrosurgical operations, mostly resections of the prostate or bladder (ELSÄSSER, ROOS, SCHMIEDT).

In all surgical interventions involving high-frequency alternating current, the organism of the patient becomes part of an electrical circuit. The high-frequency current delivered by the generator enters the organism at the punctiform cutting electrode and flows via paths (the details of which are unknown) to the large-area, passive neutral electrode, grounded inside the HF generator, and thus to ground potential (Figure 1).

ELECTROSURGICAL UNIT

TERMINAL FOR NEUTRAL ELECTRODE, GROUNDED

OPERATING TABLE, GROUNDED

BURN FROM LOCALIZED CONTACT WITH THE OPERATING TABLE

Figure 1: Electrosurgical circuit with conventional grounded neutral electrode. The high-frequency current in this case always flows from the active electrode to ground via the path of least resistance.

Immediately beneath the punctiform active electrode, the current, entering with high density, encounters the high electrical resistance of the tissue. According to JOULE's law: heat = current strength² x resistance x time, such high temperatures develop in the tissue under the active electrode that the tissue structure bursts owing to vaporization of the fluid in the tissue, producing the intended parting of the tissue. Because the current usually spreads in the tissue immediately, its density drops very quickly and the current is therefore tolerated without incident during its further progress through the organism to the neutral electrode.

According to the laws of electrophysics, current will always flow along the path of least resistance between potentials. Usually this path is offered in the form of the neutral electrode (Figure 1).



- 1 -



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If, however, the patient comes into contact with other grounded metal parts - the operating table, for example - the current can also flow from that point to ground, particularly if such points of contact with the operating table are very close to the operation site or if, as a result of improper attachment, the neutral electrode offers higher resistance to the current transfer. If such contact points with grounded conductors are small in area, the current density again becomes very high and can lead to burns (Figure 1).

This basic risk of unintended electrical injury to tissue away from the operation site is particularly high in the case of urological interventions, for the following three reasons:

1. Particularly high current applications are required for cutting and coagulation operations under water.
2. Conventional resectoscopes, which are composed of current-carrying (cutting loop) and non-current-carrying metal parts, represent capacitors which also permit a capacitive transfer of the high-frequency current to the metal parts insulated from the current-carrying elements.

ELSÄSSER, ROOS and SCHMIEDT indicated in 1974 that about 20% of the high-frequency output delivered to the cutting loop is lost capacitively as so-called "leakage current" at the resectoscope shaft.

More recent and more extensive studies on a phantom (Roos) have shown that - with a secondary connection via the irrigation liquid - current can in addition pass from the cutting loop to those parts of the resectoscope inundated with irrigation liquid (shaft and optical system). The resectoscope shaft is thus significantly charged, both capacitively as well as via the irrigation liquid (Figures 2, 3, and 4).

LOOP - IRRIGATION LIQUID - SHAFT SHUNT
TOGETHER YIELD THE TOTAL LEAKAGE CURRENT
LOOP - SHAFT CAPACITANCE
OUTFLOWING LEAKAGE CURRENT
RESECTOSCOPE SHAFT
CUTTING LOOP

Figure 2: Current-flow distribution with conventional transurethral resection.

Figure 3: Current loading of the urethra in the case of conventional TUR by leakage currents. In addition to the capacitive leakage current, the current flows directly from the cutting loop to those parts of the resectoscope projecting into the irrigation liquid.

HF UNIT

J1 - CURRENT FLOW

CUTTING LOOP —————> NEUTRAL ELECTRODE

J2 - CURRENT FLOW

IRRIGATION LIQUID

SHAFT - NEUTRAL ELECTRODE

LOOP CAPACITANCE

Figure 4: Equivalent circuit for Figures 2 and 3.

3. The sum of the leakage currents flows via the urethral tissue lying up against the shaft to the neutral electrode; this usually takes place unnoticed and without negative consequences, because the resectoscope shaft with its large surface represents a passive electrode. If for any reason (preexisting urethral stricture, gaps in the insulating lubricant film) the current transfer takes place preferentially - or even exclusively - to a small circumscribed point on the shaft, the excessive current density at this point can lead to electrothermal damage to the tissue. Due to the particular anatomical conditions in men - the majority of urological patients are of course men - the sum of all the leakage currents delivered to the urethra must also pass the root of the penis, before they can spread in the true pelvis, so that the urethra must necessarily be exposed to a particularly high current loading in the region of this constriction point, which under certain circumstances can no longer be tolerated in some individuals.

To protect the urethra from this high current loading with possible electrothermal damage, resectoscopes have recently been built in which the shaft either consists entirely of a nonconductive material (Teflon®) or is insulated by covering it with a Teflon tube.

But the use of such resectoscopes is also not without risk. The nonconductive shaft of course prevents the passage of the leakage currents from the resectoscope shaft to the urethra, but not the capacitive charging of the metal parts located inside the shaft. Because the insulation prevents the equalizing of potential via the urethra and the neutral electrode, the leakage current seeks another path to ground. This path leads of necessity through the operator, who must be considered grounded over a resistance which is not very high due to his unavoidable body capacitance relative to ground potential. Unpleasant discharge phenomena in the operator's face, which can sometimes be dangerous, are the result (Figure 5). Localized discharges are also frequent at other points, for example, during contact between the operator's arms and the grounded armrests of the operating table.

Figure 5: Danger of burns to the operator's face: In the case of an insulated endoscope shaft, the leakage current does not flow away via the urethra of the patient, but seeks a pathway to ground through the operator.

But the patient, too, can suffer electrical injuries. If it is necessary to insert the instrument deeply in the case of a relatively long penis, contact of the glans with the metal parts at the end of the Teflon shaft can - as in one of the authors' own cases - lead to circular burning around the meatus externus. Particularly dangerous is the use of instruments with a Teflon-covered metal shaft. The slightest defects in the Teflon coating immediately become the site of intensive current transfer and thermoelectric injury to the urethra.

Following the apparent failure of efforts to contain leakage currents through insulation, the obvious alternative was to take the opposite approach, namely, to offer the high-frequency current a path to balance the potential difference that would be so short and offering such low resistance that aberrant currents or leakage currents do not even occur.

This is effected:

1. by moving the large-area, passive neutral electrode extremely close to the active cutting electrode, which permits a potential equalization between the two electrodes within the smallest possible space, namely within the operating zone, i.e. the bladder, without other tissue being included in the current path. The current flows directly from the cutting loop to the neutral electrode through the adjacent tissue to be cut and the irrigation liquid.

2. by connecting both electrodes to a high-frequency generator with an ungrounded "floating output" circuit.

Because in the case of this ungrounded circuit none of the electrode lines carries ground potential, there is also no voltage in opposition to ground potential. No current can thus flow from the operating zone to ground.

This principle of the use of bipolar electrodes in conjunction with an ungrounded, floating high-frequency circuit has been described by HIRSCH and ROOS in the field of gynecology, for laparoscopic tube sterilization, and by MELCHIOR for stanching the blood using bipolar microcoagulation.

In the urological resectoscope, the neutral electrode and active electrode can be structurally combined into a bipolar electrode by incorporating the neutral electrode - as Figures 6 and 7 show - as a metal plate over the cutting loop.

INSULATION

LARGE-AREA ANTIPOLE TO THE CUTTING LOOP (NEUTRAL ELECTRODE)

INSULATION

OPERATING PRINCIPLE

Figure 6: Bipolar electrode arrangement for cutting in the case of transurethral resection. The current flows from the cutting loop directly to the nearby lamelliform neutral electrode.

LARGE-AREA ANTIPOLE TO THE CUTTING LOOP

Figure 7: Electrical voltage field limited to a restricted area, during cutting with a bipolar cutting loop under water.

However, this bipolar electrode arrangement presents certain difficulties from the point of view

of operating technique: The arrangement of the metal plate above the cutting loop apparently disturbs the conditions of flow, so that the formation of bubbles in the irrigation liquid greatly impairs the view of the operating field. A skilled resectoscope manufacturer may, however, be able to resolve this problem.

A second possibility, the incorporation of the neutral electrode as a metal ring into the end of the resectoscope shaft near the bladder (Figures 8 and 9), has on the other hand been found to be without problems from the standpoint of operating technique and have proved successful.

METAL RING AS LARGE-AREA ANTIPOLE TO THE CUTTING LOOP (NEUTRAL ELECTRODE)

SECTIONAL VIEW

INSULATING MATERIAL
OPTICAL SYSTEM
POWER SUPPLY

Figure 8: Arrangement of bipolar electrodes for transurethral resection. The neutral electrode is attached as a metal ring to the end of the resectoscope shaft.

Figure 9: Photograph of the instrument from Figure 8. The neutral electrode is positioned as a metal ring at the end of the resectoscope shaft.

Measurements on a phantom have already shown that the use of both the bipolar and the annular electrode yield very good electrical conditions due to the new current path. The resectoscope shaft and the tissue adjacent to it are not subject to loading from leakage currents, the organism (with the exception of the small area between the two electrodes) does not form part of the circuit, and aberrant currents can only be derived or measured in minimal strength.

We have provided a conventional resectoscope with a resectoscope shaft carrying the neutral electrode, like that shown in Figures 8 and 9, and connected the resectoscope's standard cutting loop and the neutral electrode to an HF surgical unit with floating output, adapted to the special electrical conditions and made available to us by the Martin company. [Footnote: Firma Gebrüder MARTIN (Martin Brothers), D-7200 Tuttlingen]

With this unit (Figures 8 and 9), which we modified ourselves as described above, we have to date performed a total of 27 prostate electroresections and 5 bladder electroresections, all without complications. The cutting capability of the loop was in no way impaired by the new current pathway. Smooth, clean-edged cuts can be executed effortlessly, at least as well as with conventional instruments.

The same is true for stanching of the blood, with the coagulation electrode achieving excellent results.

To test the new electrical conditions, we took measurements with five of the total of 32 patients. The layout of the measuring instruments and the measurement intervals are shown in Figure 10.

RESECTOSCOPE SHAFT

BIPOLAR CUTTING LOOP

HF UNIT, UNGROUNDED

Figure 14: Arrangement of the measuring instruments for recording the leakage currents during transurethral resections. See text for explanation.

I_1 = Leakage current from the resectoscope to a neutral electrode fixed to the thigh (when the shaft is not insulated, this outflow or leakage current flows back via the urethra to the neutral electrode).

U_1 = Electrical potential between the resectoscope and the neutral electrode.

I_2 = Leakage current from the resectoscope to ground (cause of frequent burns to the face of the operator)

U_2 = Electrical potential between the resectoscope and ground.

I_3 = Leakage current from the patient to ground (cause of burns to the patient in the case of small-surface contacts with conductive parts of the operating table carrying ground potential).

U_3 = Electrical potential between patient and ground.

The following measuring instruments were used:

Current meter: Neuberger milliammeter with thermal interface.
Measurement range: 0-150 mA and 0-600 mA.

Voltage meter: Cathode-ray oscilloscope from Advance Electronics, Type OS 3000.

In the case of each of the patients being operated on, the initial cuts were made with a conventional resectoscope with Teflon insulation, and the resulting leakage currents and voltages arising during the cutting operation were measured. The connection was made to metal parts of the instrument near the operator.

After recording the measurement data, the instrument was changed, and the operation was completed using the new resectoscope, as modified by us, with bipolar current application and ungrounded HF generator with floating output.

The same measurements were then taken during the cutting procedure on the same patient, under the same conditions, with the position unchanged.

The table shows the averages from the measurement data obtained, with the upper line showing the results for the conventional technique and the lower line those for the new instrument.

At 150 mA, the leakage current measured using the conventional technique is so large that burns must in any event be anticipated at small contact points with grounded conductors, no matter where this contact arises: in the patient's urethra or on the patient's skin or on the operator's skin.

The readings obtained during use of the new bipolar technique lie below the critical region, and they can probably be reduced still further by structural improvements in the resectoscope or in the feed cable.

Table: Measurement data; for circuit diagram see Figure 19

Operating technique	I_1	U_1	I_2	U_2	I_3	U_3
Conventional with grounded neutral electrode	Shorted, both grounded				Opened, directly shorted	
	150 mA	300 V				
New bipolar technique	15 mA	30 V	15 mA	30 V	<5 mA	<10 V

Summary

This subject of the report is a resectoscope with a new arrangement of the electrodes, which operates with a high-frequency circuit having no leakage current. It has thus far been used to complete 32 resections without complications.

The high-frequency current, delivered by an ungrounded high-frequency generator with a floating output circuit, flows directly from the active cutting electrode, through the tissue to be cut and the irrigation liquid, to the annular neutral electrode at the proximal end of the resectoscope shaft. The current flow in the organism remains within the small operation zone, inside the bladder. Because the lines to the two electrodes exhibit no voltage above ground potential, no current can flow from the operation area to ground. As a result, with the new method - in contrast to the conventional one - no significant leakage currents can be measured which could cause electrical injuries to the patient's urethra or skin.

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Keywords:

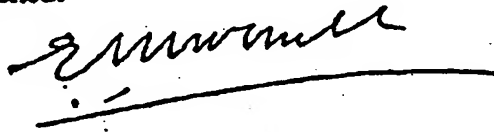
Transurethral resection without leakage of current - new instrument
[in German, English, French and Spanish]

Authors' addresses: Priv.-Doz. Dr. E. Elsässer, Krankenhaus der Barmherzigen Brüder, Urologische Abteilung [Brothers of Charity Hospital, Department of Urology], Romanstrasse 93, D-8000 Munich 19 [Federal Republic of Germany]

E. Roos, Ing. VDI, Fa. Gebr. Martin, D-7200 Tuttlingen [Federal Republic of Germany].

Washington, DC
August 18, 1998

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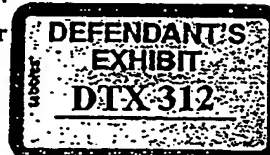
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require flushing of the region to be treated with normal saline, both to maintain an isotonic environment and to keep the field of viewing clear. The presence of saline, which is a highly conductive electrolyte, can cause shorting of the electrosurgical electrode in both monopolar and bipolar modes. Such shorting causes unnecessary heating in the treatment environment and can further cause non-specific tissue destruction.

Present electrosurgical techniques used for tissue ablation also suffer from an inability to control the depth of necrosis in the tissue being treated. Most electrosurgical devices rely on creation of an electric arc between the treating electrode and the tissue being cut or ablated, causing the desired localized heating. Such arcs, however, often create very high temperatures causing a depth of necrosis greater than 500 μm , frequently greater than 800 μm , and sometimes as great as 1700 μm . The inability to control such depth of necrosis is a significant disadvantage in using electrosurgical techniques for tissue ablation, particularly in arthroscopic procedures for ablating and/or reshaping fibrocartilage, articular cartilage, meniscal tissue, and the like.

In an effort to overcome at least some of these limitations of electrosurgery, laser apparatus have been developed for use in arthroscopic and other procedures. Lasers do not suffer from electrical shorting in conductive environments, and certain types of lasers allow for very controlled cutting with limited depth of necrosis. Despite these advantages, laser devices suffer from their own set of deficiencies. In the first place, laser equipment can be very expensive because of the costs associated with the laser light sources. Moreover, those lasers which permit acceptable depths of necrosis (such as excimer lasers, erbium:YAG lasers, and the like) provide a very low volumetric ablation rate, which is a particular disadvantage in cutting and ablation of

A central aspect of the present invention is the ability of the probe 10 to deliver high energy flux levels effectively only to the intended areas, i.e., the target tissue, and not to surrounding healthy tissue or electrically conducting fluids (e.g., normal saline irrigant). Such directed energy transfer results in selective heating of the target tissue which allows the probe to cut, ablate or recontour the target tissue. Referring to Fig. 4, when the tip 12 of the probe 10 is pressed against a region of target tissue 80, some of the electrode terminals 50 will be in contact with target tissue, while other electrode terminals may be in contact with electrically conducting fluid 70. Each of the electrode terminals 50 experiences an electrical impedance which is characteristic of the material which is disposed between the individual electrode terminals 50 and the common electrode 54. The present invention takes advantage of the fact that the electrical resistivity of typical target tissue at frequencies of 50 kHz or greater (e.g., fibrocartilage and articular cartilage) is higher by a factor of approximately four or more than that of the surrounding electrically conducting fluid 70 typically used as an irrigant during arthroscopic and endoscopic procedures. Thus, if the current passing through each of the electrode terminals 50 is limited to a preselected maximum value, the regions of higher electrical resistance will generate more Joulian heating (power = I^2R , where I is the current through resistance, R) than a region of lower electrical resistance.

In contrast to the present invention, electrosurgical methods and apparatus of the prior art involving a single electrode exhibit substantially reduced effectiveness when a portion of the exposed electrode is in contact with a low resistance pathway (e.g., normal saline irrigant). In those circumstances, the majority of power delivered from the single electrode tip is dissipated within the low resistance electrically

This appendix designation corresponds to a video admitted at trial as exhibit DTX – 315.

DTX – 315 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.

**This range erroneously was used to refer to
admitted exhibit DTX – 315. The proper
designation for DTX – 315 is A19249.**

A19250 – A19253

This appendix designation corresponds to a video admitted at trial as exhibit DTX – 316.

DTX – 316 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.

241-95-474
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4-15-5-5-1

Form PTO-436
(Revised 7-75)

686600		PATENT DATE SEP 26 1970		PATENT NUMBER	
SERIAL NO. (Series of 1970)	FILING DATE	CLASS	SUBCLASS	GROUP ART UNIT	EXAMINER
686-600	05/14/76	128	333.15	335	Cohen
APPLICANT: FRIEDRICH ROOS, TUTTLINGEN, GERMANY.					
TITLE OF INVENTION: ELECTRO - SURGICAL DEVICE					
SEND CORRESPONDENCE TO: ROBERT OSANN, SALOMON, OSANN, KRAMER, DYORAK, GENOVA & TRAU, 35 CROOK ST., NEW YORK, N. Y. 10004-1004 <i>the World Trade Center file 776</i>					
PERSONAL ATTORNEY: ROBERT OSANN, F.T. 11					
ASSOCIATE ATTORNEY: F.T. 11					
SER. NO.	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	P.O.P. CLAIMS	FILING REC RECEIVED
686-600	USA	6	33	1	8111
CONTINUING DATA		VERIFIED EXAMINER INITIALS			
None		R.S.C.			
CLAIMS PRIORITY FOREIGN APPLICATION YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> MEETS CONDITIONS SPECIFIED IN 35 USC 117 YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> GERMANY, FED. REP. 25217190 05/15/75					ASSIGNOR
PARTS OF APPLICATION FILED SEPARATELY					U.S. DEPT. OF COMMERCE - PATENT AND TRADEMARK OFFICE FORM PTO-436A (5-75)
					4-70 PREPARED FOR ISSUE 11-91-78 11-91-78 EXAMINED AND PASSED FOR ISSUE LEE S. COHEN R.S.C. 335 Lee S. Cohen Primary Examiner Date of printed pages Drawing fee \$118. Date of issuance and issue fee due (see 1) Date mailed
THIS SPACE RESERVED FOR RETENTION LABEL		THIS SPACE RESERVED		373079	

DEFENDANT'S
EXHIBIT
DTX 321

S&N 0036928

A 19259

references either alone or in combination. Prior to explaining by which features the invention differentiates over the cited art, it should be mentioned that Applicant claims the combination of an endoscope as for instance shown in Fig. 1 with an electro-surgical device of the Fig. 2 embodiment, as previously elected. In this connection Applicant respectfully directs the Examiner's attention to Page 9, Lines 25 to 27 and Page 13, Lines 18 to 22. Applicant trusts that no new figure showing the electro-surgical device of Fig. 2 with the endoscope of Fig. 1 is required. Still furthermore, if a generic claim such as Claim 34 is ultimately held allowable, Applicant respectfully requests that Claims 51 to 53 specifically directed to the embodiment of Figs. 7 and 8 be allowed. At present, only Claims 34 to 50 and 54 to 56 read on the elected species of Fig. 2.

Claim 34 differentiates over the cited art by several features. First, at the tip of the endoscope an insulating projection (such as projection 18 in Fig. 1) is provided and the neutral electrode (11) is arranged at a distinct distance from the front edge of the insulating projection. The purpose of this arrangement is that material cut away by the treatment electrode (12) is kept away from the neutral electrode when the treatment electrode is retracted, for instance into the position shown in Fig. 1. If the insulating projection were not provided, there exists the danger that the removed material could short-circuit electrodes 11 and 12.

Secondly, the neutral electrode (11) must be mounted in the interior of the endoscope behind the front edge of the

insulating projection (18) so that it cannot come into contact with the tissue of the human body. This effect is described on Pages 15, 16 (however, in connection with the Fig. 7, 8 embodiment).

Thirdly, washing liquid (29) must be allowed to flow out of the endoscope so as to provide the necessary electrical conductor between the treatment electrode (12) and the neutral electrode (11). This washing liquid would form the resistor R (see Fig. 4). In this connection, the washing fluid would conduct electrical current just as the tissue fluid and the tissue itself of the human body.

The combination of the above features as recited in new claim 34 and the claims dependent thereon is not anticipated or even remotely suggested by the cited references.

Reference A does not disclose the feature of the washing fluid so that the indifferent electrode 24, 25, 26 has to project from the instrument. The disadvantage is that under certain conditions burning of the tissue at the electrode 26 can take place and that the current path between the indifferent electrode 26 and the active cutting electrode 22 is rather indefinite. A further disadvantage of the known instrument is that the indifferent electrode 24, 25, 26 is not insulated from the stem 10. Thus it is connected to earth potential. Thus the known instrument has all the disadvantages described in the introduction of the present application.

According to the concept of the present invention there is always a well-defined current path between the cutting

electrode 12 and the neutral electrode 11 through the washing (and tissue) fluid. Since the neutral electrode does not contact the tissue there is no danger of an undesired burning of the tissue by the neutral electrode.

Reference B shows an instrument in which the cutting tool 12 carries two windings 1, 2 forming the two electrodes. Save for the very complicated structure of this tool there are high capacitive losses between the two windings. Furthermore it has turned out that burned tissue will collect on the bottom of the insulator 4 between adjacent wires 1, 2.

References C and D show instruments where both electrodes project from the distal end of the endoscope. Thus both electrodes come into contact with the tissue of the human body. Burning of the tissue will take place at both electrodes. In the present invention only one electrode, namely the cutting electrode 12 is burning the tissue whereas the neutral electrode does not influence or affect the tissue in any way.

Reference E shows an insulating projection at the distal end of the endoscope. Furthermore obviously there is provided a washing fluid channel in the shaft of the endoscope. However the reference does not disclose the provision of a large-area neutral electrode at a certain distance from the front edge of the insulating projection.

The important feature of the invention that the cutting electrode as well as the neutral electrode are connected to the high frequency generator by conductors insulated from the shaft of the endoscope, is not disclosed in the reference. Also

10

Record of invention

Invented by
Philip E. Eggers

conceived & understood by Andrew Eggers Jan 31 1973

Technique for Ablation of Meniscus
Using High Frequency Current
With Minimal Tissue Damage.

Conventional electro-surgery methods
cut (ablate) meniscus with single electrode
operating at ^{peak} voltages of up to 3000 to 5000 Volts.
By using much smaller electrodes and
a multiplicity of electrodes, it has been
demonstrated that ablation can be performed
at much lower voltage levels. This invention
envisions use of multiple electrodes in either
monopolar mode or bipolar mode with
electrode tips having small radii of
curvature or small size to increase electric
field intensity in proximity to tissue to effect
ablation. An experiment performed today
good ablation of (chicken) meniscus (in vitro)
in saline (but meniscus ^{partially} surface of cartilage)
(monopolar) was used
a standard steel electrode was used
(0.040" o.d., 0.005" wall hypodermic needle)
and good ablation was achieved at
voltages between 160V and 180V (RMS) at (50-100)
200 KHz ^(50-100 KHz) current in range of 100 to 500 mA.
Above 200V rms, charring/browning of tissue
occurred. Small electrodes with minimum depth
Philip E. Eggers January 23, 1973.

CONFIDENTIAL
ATTORNEYS EYES ONLYARTC 17713
HIGHLY CONFIDENTIAL
ATTORNEYS EYES ONLY

A 19783

This appendix designation corresponds to a video admitted at trial as exhibit DTX – 897.

DTX – 897 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.

IN 904993

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

December 12, 2002

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE
RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS
OF:

APPLICATION NUMBER: 09/098,205
FILING DATE: July 27, 1998
PATENT NUMBER: 6,224,592
ISSUE DATE: May 01, 2001



By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

P. R. Grant
P. R. GRANT
Certifying Officer



PART (1) OF (3) PART(S)

A 20082



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/098,205	07/27/98	EGGERS	P A-2-2

021394
ARTHROCAPE CORPORATION
595 N PASTORIA AVENUE
SUNNYVALE CA 94086

GM12/1115

EXAMINER

COHEN, L

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED:

11/15/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

A 20498

Office Action Summary

Application No. 09/098,206	Applicant(s) Eggers et al
Examiner Lee S. Cohen	Group Art Unit 3739

responsive to communication(s) filed on Oct 28, 1999

this action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Extended statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is later, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of FR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 80-137 is/are pending in the application.
- Of the above, claim(s) 103-137 is/are withdrawn from consideration.
- ☒ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 80-102 is/are rejected.
- ☒ Claim(s) _____ is/are objected to.
- ☒ Claims _____ are subject to restriction or election requirement.

Drawings

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

Priority

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

References

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 25
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Application/Control Number: 09/098,205

Page 2

Art Unit: 3739

Claims 103-137 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 6.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83, 84, 87, 89-92, 94-96, 101, and 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 83, 84, 87, 89, and 94 - "the electrically conductive fluid" fails to accurately reference its antecedent. Claim 90 - "the probe" and "the distal tip of the probe" lack antecedent basis. Claim 101 - the inner member appears to be electrically connected to itself. Claim 102 - "the inner lumen" lacks antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 of this title before the invention thereof by the applicant for patent.

Claims 80-85, 88, 89, 92-96, and 98-102 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Baker (5,514,130). Applicant's attention is directed to column 8, lines 26-

36.

A 20500

Art Unit: 3739

Claims 80-84 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Knowlton (5,871,524). In Knowlton, the membrane is filled with electrolytic fluid. Electrodes 26 are positioned at various places in the membrane (col. 4, lines 57-64). The electrodes can be either monopolar or bipolar (col. 5, lines 34-38). Therefore, when employing bipolar electrodes, a current path will be generated between the active and return electrodes of the bipolar electrode.

Claims 80-85, 92, 94-96, 98, and 99 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Abele (5,860,974). Applicant's attention is directed to column 6, lines 48-54 and column 8, lines 33-47.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of Knowlton, Baker, or Abele in view of Lax et al (5,569,242). The particular fluid for similar methodology is taught by Lax et al at column 7, lines 30-31. Accordingly, it would have been within the level of skill of the artisan to select saline to optimize performing the treatment.

Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baker or Abele. The particular voltage would have been within the level of skill of the artisan to select to optimize performing the treatment.

Art Unit: 3739

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 80-83, 85-91, and 93 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 7, 8, 10, 12, 19, 20, 38, and 40 of prior U.S. Patent No. 5,891,095. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Orman*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321^o may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Application/Control Number: 09/098,205

Page 5

Art Unit: 3739

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


Claims 84, 92, and 94-102 are rejected under the judicially created doctrine of double patenting over claims 1-64 of U. S. Patent No. 5,891,095 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method of applying electrical energy to a target site.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The status of the applications referenced in the background of the invention should be updated and Attorney Docket numbers should be deleted.

Any inquiry concerning this communication should be directed to Lee S. Cohen at telephone number (703) 308-2998.


Lee Cohen
Primary Examiner

A 20503

Notice of References Cited

Application No.
08/098,205

Applicant

Eggers et al

Examiner

Lee S. Cohen

Group Art Unit

3739

Page 1 of 1

U.S. PATENT DOCUMENTS

	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS
A	5,860,974	1/1999	Abels	606	41
B	5,871,524	2/1999	Knowlton	607	101
C	5,881,005	4/1999	Eggers et al	604	114
D					
E					
F					
G					
H					
I					
J					
K					
L					
M					

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS
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O						
P						
Q						
R						
S						
T						

NON-PATENT DOCUMENTS

	DOCUMENT (Including Author, Title, Source, and Pertinent Pages)	DATE
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V		
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on January 24, 2000
By Kehring



K.T.

#8/B

Attorney Docket No. A-2-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PHILIP E. EGGERS et al.

Application No.: 09/098,205

Filed: July 27, 1998

For: SYSTEMS AND METHODS FOR
ELECTROSURGICAL TISSUE
TREATMENT IN CONDUCTIVE FLUID

Examiner: L. Cohen

Art Unit: 3739

AMENDMENT

RECEIVED
FEB - 3 2000
TECHNOLOGY CENTER 3700

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed November 15, 1999, please amend the above-identified application as follows.

IN THE SPECIFICATION:

On page 1, please delete the first paragraph (lines 8-21) and insert the following:

The present invention is a continuation-in-part of Application No. 08/485,219, filed June 7, 1995, now U.S. Patent No. 5,697,281, which is a continuation-in-part of Application No. 08/446,767 filed June 2, 1995, now U.S. Patent No. 5,697,909 which is a U.S. National Phase Filing of International Application No. PCT/US94/05168, filed May 10, 1994, which is a continuation-in-part of Application No. 08/059,681, filed May 10, 1993, now abandoned, which is a continuation-in-part of Application No. 07/958,977, filed October 9, 1992, now U.S. Patent No. 5,366,443, which is a continuation-in-part of Application No.

division of Application No. 08/795,686, filed February 5, 1997, now U.S. Pat. No. 5,841,493 which is a division of Application No. 08/561,958, filed Nov. 22, 1995, now U.S. Pat. No. 5,697,682, which is a

A 20533

07/817,575, filed January 7, 1992, now abandoned, the full disclosures of which are incorporated herein by reference.

IN THE CLAIMS:

Please cancel claim ~~82~~, amend claims 80, 81, 83, 90 and 99-102 and add new claims 138-159 as follows:

80. (Amended) A method for applying electrical energy to a target site on a body structure on or within a patient's body, the method comprising:
positioning an electrode terminal into at least close proximity with the target site in the presence of an electrically [conducting] conductive fluid;
positioning a return electrode within the electrically [conducting] conductive fluid such that the return electrode is not in contact with the body structure to generate a current flow path between the electrode terminal and the return electrode; and
applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the region of the target site; and to the return electrode through the current flow path.

81. (Amended) The method of claim 80 wherein the electric current flows substantially through the electrically-[conducting] conductive fluid while minimizing electric current flow passing through the body structure.

82. Canceled.

83. (Amended) The method of claim 80 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate the current flow path between the [target site] electrode terminal and the return electrode.

90. (Amended) The method of claim 80, wherein the return electrode is located

A 20535

TM 504393

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

December 12, 2002

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RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS
OF:

APPLICATION NUMBER: 09/098,205
FILING DATE: July 27, 1998
PATENT NUMBER: 6,224,592
ISSUE DATE: May 01, 2001



By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

P. R. Grant
P. R. GRANT
Certifying Officer



PART (2) OF (3) PART(S)

A 20536

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on a distal end of an instrument shaft [the probe], further comprising an insulating matrix [at the distal tip of] on the probe between the return electrode and the electrode terminal, the insulating matrix comprising an inorganic material.

99. (Amended) The method of claim 84 wherein the electrode terminal is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically [conducting] conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the electrode terminal

100. (Amended) The method of claim 84 further including positioning a distal end of a fluid supply shaft adjacent the electrode terminal, the delivering step comprising directing the electrically [conducting] conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the electrode terminal.

B5
101. (Amended) The method of claim [99] 84 wherein the electrode terminal is located on a distal end of a probe and the return electrode is an inner tubular member defining an axial lumen [electrically connected to the inner tubular member], the delivering step including directing electrically [conducting] conductive fluid through the [inner] axial lumen to the distal end of the probe over the electrode terminal.

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102. (Amended) The method of claim 99 wherein the return electrode is an outer tubular member defining an axial passage between the outer surface of the probe and the inner surface of the outer tubular member, the delivering step including directing the electrically conducting fluid through the [inner lumen] axial passage to the distal end of the probe over the electrode terminal.

Please add the following new claims:

128. (New) A method for applying electrical energy to a target site on a body structure on or within a patient's body the method comprising:

C³
contacting an active electrode with the body structure in the presence of an electrically conductive fluid;
spacing a return electrode away from the body structure in the presence of the electrically conductive fluid; and
applying a high frequency voltage difference between the electrode terminal and the return electrode such that an electrical current flows from the electrode terminal, through the electrically conductive fluid, and to the return electrode.

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139. (New) The method of claim 138 wherein the electric current flows substantially through the electrically conductive fluid while minimizing electric current flow passing through the body structure.

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140. (New) The method of claim 138 wherein at least a portion of the electric current passes through the body structure.

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141. (New) The method of claim 138 further comprising immersing the target site within a volume of the electrically conductive fluid and positioning the return electrode within the volume of electrically conductive fluid to generate a current flow path between the electrode terminal and the return electrode.

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142. (New) The method of claim 138 further comprising delivering the electrically conductive fluid to the target site.

CS
143. (New) The method of claim 138 wherein the electrode terminal comprises a single active electrode disposed near the distal end of an instrument shaft.

144. (New) The method of claim 138 wherein the electrode terminal includes an array of electrically isolated electrode terminals disposed near the distal end of an instrument shaft.

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145. (New) The method of claim 138 wherein the electrically conductive fluid comprises isotonic saline.

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Cup

146. (New) The method of claim 138 including independently controlling current flow to the electrode terminal based on electrical impedance between the electrode terminal and the return electrode.

B6

147. (New) The method of claim 138 wherein the return electrode is spaced from the electrode terminal such that when the electrode terminal is brought adjacent a tissue structure immersed in electrically conductive fluid, the return electrode is spaced from the tissue structure and the electrically conductive fluid completes a conduction path between the electrode terminal and the return electrode.

148. (New) The method of claim 138, wherein the return electrode is located on a distal end of a probe, further comprising an insulating matrix at the distal tip of the probe between the return electrode and the electrode terminal, the insulating matrix comprising an inorganic material.

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149. (New) The method of claim 148 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

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C2

150. (New) The method of claim 138 further comprising applying a sufficient voltage difference between the return electrode and the electrode terminal to effect the electrical breakdown of tissue in the immediate vicinity of the electrode terminal.

151. (New) The method of claim 138 further comprising measuring the temperature at the target site and limiting power delivery to the electrode terminal if the measured temperature exceeds a threshold value.

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h

C7 152. (New) The method of claim 138 further comprising applying a sufficient high frequency voltage difference to vaporize the electrically conductive fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

40 39 153. (New) The method of claim 152 wherein at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum.

41 39 154. (New) The method of claim 152 wherein at least a portion of the energy is in the form of energetic electrons.

42 27 155. (New) The method of claim 138 wherein the voltage is in the range from 500 to 1400 volts peak to peak.

B4 156. (New) The method of claim 138 further comprising generating a voltage gradient between the electrode terminal and tissue at the target site, the voltage gradient being sufficient to create an electric field that causes the breakdown of tissue through molecular dissociation or disintegration.

157. (New) The method of claim 138 wherein the electrode terminal is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the electrode terminal

158. (New) The method of claim 138 further including positioning a distal end of a fluid supply shaft adjacent the electrode terminal, the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the electrode terminal.

Philip E. Eggers et al.
Serial No. 09/098,205
Page 7

159. (New) The method of claim 138 wherein the return electrode is an outer tubular member defining an axial passage between the outer surface of the probe and the inner surface of the outer tubular member, the delivering step including directing the electrically conductive fluid through the axial passage to the distal end of the probe over the electrode terminal.--

REMARKS

Claims 80, 81 and 83-159 are pending. Applicant has amended claims 80, 81, 83, 90 and 99-102 to address the Examiner's 112 rejections on page 2 of the Office Action. Applicant disagrees with the Examiner's double patenting rejections on pages 4 and 5 of the Office Action. However, to expedite prosecution, applicant has amended claim 80 to address the Examiner's double patenting rejection on page 4. In addition, applicant has submitted a terminal disclaimer concurrently with this response to obviate the obviousness-type double patenting rejection on page 5 of the Office Action.

The claims stand rejected as being anticipated or obvious over Baker, Knowlton, Abele and Lax. Applicant disagrees with these rejections. None of the cited references disclose or suggest the affirmative step of positioning a return electrode within electrically conductive fluid to generate a current flow path between the active and return electrodes, as is recited in claim 80. However, to expedite prosecution, applicant has amended independent claim 80 to even more clearly distinguish over the prior art. Claim 80 now recites the step of positioning a return electrode within the electrically conductive fluid such that the return electrode is not in contact with the body structure. Baker, Abele and Lax clearly do not disclose or suggest this step. As stated in col. 3, lines 58-63 and col. 6, lines 63-66 of Baker, the return electrode must function as a grounding pad and thus is in contact with the tissue. The ablation band is formed along the tissue between the two distal ends of the electrodes, which are both in contact with the tissue. In the Abele device, the electrodes are designed to press against the heart tissue with the desired contact pressure. Similarly, the Lax device must have contact between both the active and return electrodes and the patient's tissue.

Philip E. Eggers et al.
Serial No. 09/098,205
Page 8



In the Knowlton device, the thermal electrodes 26 are placed in a porous membrane 18, and an electrolytic solution 20 is introduced into the porous membrane to transfer RF current or power from RF electrodes 28 to the underlying collagen tissue (col. 5, lines 25-32). The monopolar mode is described (col. 5, lines 34-37) as having a return electrode in the form of a conductive pad applied to the patient's outer skin. The reference states that RF electrodes 26 can be monopolar or bipolar (line 33). However, the reference does not describe how a bipolar device would work to transfer the RF power to the underlying collagen tissue. For example, if electrodes 26 were both the active and return electrodes, the RF current or power would simply pass from one of the electrodes 26 through the conductive solution within membrane 18 to the other of the electrodes 26 (i.e., without transferring any RF power to the underlying tissue). Thus, even in the bipolar embodiment (which is not described), the return electrode must be in contact with the tissue in order for the RF power to be transferred thereto. Accordingly, applicant requests that this rejection be withdrawn.

New independent claim 138 recites the steps of contacting an active electrode with the body structure in the presence of an electrically conductive fluid, and spacing a return electrode away from the body structure in the presence of the electrically conductive fluid. None of the cited references disclose or suggest these two steps. In Baker, Lax and Abele, both active and return electrodes are in contact with the tissue. In Knowlton, the active electrode 26 is not in contact with the tissue.

Applicant believes that this application is now in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (408) 736-0224.

Respectfully submitted,


John T. Raffle
Reg. No. 38,585

ArthroCare Corporation
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Sunnyvale, California 94086
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TECHNICAL CENTER 3700

FEB - 3 2009

RECEIVED

A 20542

Amendment

AnthroCare Corporation
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Sunnyvale, CA 94086
(408) 736-0224

Atty. Docket No. A-2

Date Jan 24, 2000 #2

In re application of: PHILIP E. EGGERS et al.

Application No.: 09/098,205

Filing Date: July 27, 1998

Group Art Unit: 3739

For: SYSTEMS AND METHODS FOR
ELECTROSURGICAL TISSUE TREATMENT IN
CONDUCTIVE FLUID



I hereby certify that this is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Assistant Commissioner for Patents
Washington, D. C. 20231.

Date: January 24, 2000

THE ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[] Enclosed is a petition to extend time to respond.

[] Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.

[] A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is enclosed.

[] If any extension of time is needed, then this response should be considered a petition therefor.

The filing fee has been calculated as shown below:

(Col. 1)	(Col. 2)	(Col. 3)	SMALL ENTITY	OTHER THAN SMALL ENTITY
CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDIT. FEE
TOTAL 44	MINUS 38	= 0	X9= \$	X18= \$
INDEP. 1	MINUS 3	= 0	X39= \$	X78= \$
[] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM			+130= \$	+260= \$
			TOTAL \$	TOTAL \$
			ADDIT. FEE	

- * If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.
 - ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
 - *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
- The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.

[X] No fee is due.

Please charge Deposit Account No. 50-0359 as follows:

- [] Claims fee \$
- [X] Any additional fees associated with this paper or during the pendency of this application.
Extra copies of this sheet are enclosed.

John T. Raffle
Reg. No. 38,587

A 20543

GAU3739

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On May 25, 2000
By Kahim



#1112
K Cooper
6-9-00

Attorney Docket No. A-2-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PHILIP E. EGGERS et al.

Application No.: 09/098,205

Filed: July 27, 1998

For: SYSTEMS AND METHODS FOR
ELECTROSURGICAL TISSUE
TREATMENT IN CONDUCTIVE FLUID

Examiner: L. Cohen

Art Unit: 3739

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed February 29, 2000, please amend the above-identified application as follows.

IN THE CLAIMS:

Please cancel claim 159 and amend claims 90, 102, 138, 141, 143, 144, 146-148, 150-152, 157 and 158 as follows:

90. (Twice Amended) The method of claim 80, wherein the active return electrode is located on a distal end of an instrument shaft, further comprising an insulating matrix on the [probe] instrument shaft between the return electrode and the active electrode [terminal], the insulating matrix comprising an inorganic material.

A 20553

354
157. (Amended) The method of claim 138 wherein the active electrode [terminal] is located on the distal end of a probe, and wherein the delivering step comprises supplying the electrically conductive fluid to a proximal end of an axial lumen within the probe and directing the fluid through a distal end of the axial lumen to the active electrode [terminal].

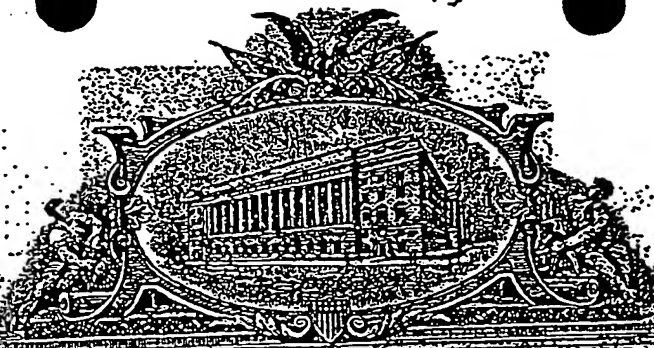
C8
158. (Amended) The method of claim 138 further including positioning a distal end of a fluid supply shaft adjacent the active electrode [terminal], the delivering step comprising directing the electrically conductive fluid through an inner lumen in the fluid supply shaft that is electrically connected to the return electrode and discharging the fluid through an open distal end of the supply shaft towards the active electrode [terminal].

REMARKS

Claims 80, 81 and 83-158 are pending. Applicant has canceled claim 159 and amended claims 90, 102, 138, 141, 143, 144, 146-148, 150-152, 157 and 158 to address the Examiner's 112 rejections on page 3 of the Office Action.

The majority of the claims stand rejected as being anticipated by Roos and Mulier. Applicant disagrees with these rejections. The instant application discloses and claims, in part, novel methods for performing, and systems used to perform, electrosurgery in the presence of electrically conductive fluid. For example, in performing electrosurgery according to the method of claim 80, the active and return electrodes of the instrument are both positioned near a tissue site in the presence of electrically conductive fluid, such as isotonic saline or Ringer's lactate. The return electrode is spaced away from the tissue such that electric current flows from the active electrode, through the conductive fluid, to the return electrode.

Independent claims 80 and 138 each require that the return electrode be spaced from the tissue. Mulier does not disclose or suggest this feature. Mulier discloses a monopolar electrosurgery device that requires a return pad attached to the patient's skin. Thus, the return electrode is always in contact with the tissue. Both electrodes 202 and 216 of the Mulier device are active electrodes that provide lesions in the tissue. Return electrodes are



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United States Patent and Trademark Office

February 19, 2003

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RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS
OF:

APPLICATION NUMBER: 08/561,958

FILING DATE: November 22, 1995

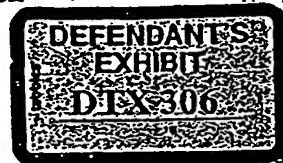
PATENT NUMBER: 5,697,882

ISSUE DATE: December 16, 1997

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



M.K. Hawkins
M.K. HAWKINS
Certifying Officer



561958



Attorney Docket No. 16238-7

PATENT APPLICATION

SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND ABLATION

Inventors:

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Hira V. Thapliyal, a United States
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Assignee:

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Status:

Small Entity

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A 21274



1

PATENT

Attorney Docket No. 16238-7

SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION

BACKGROUND OF THE INVENTION

The present invention is a continuation-in-part of application Serial No. 08/485,219, filed on June 7, 1995 ^{and still pending}, ~~(Attorney Docket 16238-0000000000)~~, which was a continuation-in-part of PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, ~~(Attorney Docket 16238-000440)~~, which was a continuation-in-part of application Serial No. 08/059,681, filed on May 10, 1993, ^{and now abandoned}, ~~(Attorney Docket 16238-000430US)~~, which was a continuation-in-part of application Serial No. 07/958,977, filed on October 9, 1992, ^{now U.S. Patent No. 5,366,443}, ~~(Attorney Docket 16238-000430US)~~, which was a continuation-in-part of application Serial No. 07/817,575, filed on January 7, 1992, ^{now abandoned}, ~~(Attorney Docket 16238-000460US)~~, the full disclosures of which are incorporated herein by reference.

1. Field of the Invention

The present invention relates generally to the field of electrosurgery and, more particularly, to surgical devices and methods which employ high frequency voltage to cut and ablate tissue.

The field of electrosurgery includes a number of loosely related surgical techniques which have in common the application of electrical energy to modify the structure or integrity of patient tissue. Electrosurgical procedures usually operate through the application of very high frequency currents to cut or ablate tissue structures, where the operation can be monopolar or bipolar. Monopolar techniques rely on external grounding of the patient, where the surgical device defines only a single electrode pole. Bipolar devices comprise both electrodes for the application of current between their surfaces.

1 15. The method of claim 1 wherein the active
2 electrode comprises an electrode array including a plurality
3 of isolated electrode terminals.

1 16. The method of claim 1 wherein the electrically
2 conducting fluid has a conductivity greater than 2 mS/cm.

1 17. The method of claim 2 wherein the electrically
2 conductive liquid comprises isotonic saline.

1 18. The method of claim 4 wherein the electric
2 field intensity is sufficient to cause molecular
3 disintegration of tissue structure on the target site.

1 19. The method of claim 15 including independently
2 controlling current flow from at least two of the electrode
3 terminals based on impedance between the electrode terminal
4 and the return electrode.

1 20. The method of claim 15 wherein the return
2 electrode is an outer tubular member, the shaft including an
3 insulating member defining an axial passage between the
4 insulating member and the outer tubular member, the directing
5 step including directing the electrically conductive liquid
6 through the inner lumen to the distal end of the shaft over
7 the active electrode.

1 21. A method as in claim 15, further including
2 maintaining a space between the electrode array and the body
3 structure during the applying step.

1 22. The method of claim 21 wherein the maintain
2 step comprises moving the electrode array transversely across
3 the body structure.

Sub B' 22
1 23. A method for applying energy to a target site
2 on a patient body structure comprising:

positioning an active electrode surface in close proximity to the target site in the presence of an electrically conducting liquid; and

applying a high frequency voltage between the active electrode surface and a return electrode surface, the high frequency voltage being sufficient to vaporize the liquid in a thin layer over at least a portion of the active electrode surface and induce the discharge of energy from the vapor layer.

24. The method of claim 23 wherein the active electrode surface comprises an electrode array including a plurality of isolated electrode terminals.

Sub B2
25. The method of claim 23 wherein the at least a portion of the energy induced from the vapor layer is in the form of photons having a wavelength in the ultraviolet spectrum.

26. The method of claim 23 wherein at least a portion of the energy induced from the vapor layer is in the form of energetic electrons.

27. The method of claim 24 wherein the isolated electrode terminals each have a contact area below 15 mm².

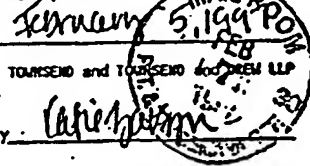
4 28. The method of claim 24 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².

Sub C2
29. The method of claim 24 wherein the electrode surface includes at least two electrode terminals.

30. The method of claim 24 wherein the electrode surface comprises between 4 to 50 electrode terminals.

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on



by

Attorney Docket No. 16238-000700

PATENT

#512

W/Election

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PHILIP E. EGGERS et al.

Examiner: M. Mendez

Application No.: 08/561,958

Art Unit: 3306

Filed: November 22, 1995

RESPONSE TO RESTRICTION
REQUIREMENT AND AMENDMENT

For: SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION

Assistant Commissioner for Patents
Washington, D.C. 20231

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GROUP 3300

Sir:

In response to the restriction requirement mailed January 7, 1997, please amend this application as follows.

IN THE CLAIMS:

Please amend claim 1, 23, 24, 29, 30, 43, 45, 48, 52, 54 and 55 as follows.

1. (Once Amended) A method for applying electrical energy to a target site on a structure within a patient's body, the method comprising:

providing an active electrode and a return electrode electrically coupled to a high frequency voltage source;

positioning (a) the active electrode into at least close proximity with the target site in the presence of an electrically conducting liquid;

positioning (a) the return electrode within the electrically conducting liquid to generate a current flow path between the target site and the return electrode; and

A

applying high frequency voltage to the active electrode and the return electrode such that an electrical current flows from the active electrode, through the body structure in the region of the target site, and to the return electrode through the current flow path.

A2

Sub B1 23. (Once Amended) A method for applying energy to a target site on a patient body structure comprising:
providing an active electrode and a return electrode electrically coupled to a high frequency voltage source;

positioning [an] the active electrode [surface] in close proximity to the target site in the presence of an electrically conducting liquid; and

applying a high frequency voltage between the active electrode [surface] and [a] the return electrode [surface], the high frequency voltage being sufficient to vaporize the liquid in a thin layer over at least a portion of the active electrode [surface] and induce the discharge of energy from the vapor layer.

24. (Once Amended) The method of claim 23 wherein the active electrode [surface] comprises an electrode array including a plurality of isolated electrode terminals.

A3

29. (Once Amended) The method of claim 24 wherein the active electrode [surface] includes at least two electrode terminals.

30. (Once Amended) The method of claim 24 wherein the active electrode [surface] comprises between 4 to 50 electrode terminals.

A4

Sub B4 43. (Once Amended) The method of claim 23 wherein the active electrode [surface] and the return electrode [surface] are spaced apart by a distance in the range from 1 to 10 mm.

Q5

Sub B7 45. (Once Amended) The method of claim 23 wherein the active electrode [surface] and the return electrode comprise a bipolar array of isolated electrode terminals.

Q6

48. (Once Amended) A method for applying energy to a target site on a patient body structure comprising:
providing an active electrode and a return electrode electrically coupled to a high frequency voltage source;
positioning [an] ~~the~~ active electrode [surface] in close proximity to the target site in the presence of an electrically conducting liquid; and
applying a high frequency voltage between the active electrode [surface] and [a] ~~the~~ return electrode [surface], the high frequency voltage being sufficient to impart sufficient energy into the target site to ablate several cell layers of the body structure without causing substantial tissue necrosis beyond the several cell layers.

Q7

52. (Once Amended) A method for applying energy to a target site on a patient body structure comprising:
providing an active electrode and a return electrode electrically coupled to a high frequency voltage source;
positioning [an] ~~the~~ active electrode [surface] in close proximity to the target site in the presence of an electrically conducting liquid; and
applying a high frequency voltage between the active electrode [surface] and [a] ~~the~~ return electrode [surface], the high frequency voltage being in the range from 600 to 1400 volts peak to peak.

Q8

54. (Once Amended) A method for applying energy to a target site on a patient body structure comprising:
providing an active electrode electrically coupled to a high frequency voltage source;
positioning [an] ~~the~~ active electrode [surface] in close proximity to the target site in the presence of an electrically conducting liquid; and

generating a voltage gradient between the active electrode [surface] and tissue at the target site, the voltage gradient being sufficient to create an electric field that breaks down the tissue through molecular dissociation.

55. (Once Amended) The method of claim 54 wherein the generating step comprises:

providing a return electrode electrically coupled to a high frequency voltage source;

applying a high frequency voltage between the active electrode [surface] and [a] the return electrode [surface]; and vaporizing the electrically conducting liquid in a thin layer over at least a portion of the active electrode surface.

REMARKS

The Examiner has restricted this application to one of the following inventions:

- (1) Claims 1-59, drawn to a method for applying electrical energy to a target site; and
- (2) Claims 60-79, drawn to an electrosurgical system for use with a high frequency power supply.

Applicant elects Group 1 without traverse. Applicant also notes that a divisional application directed to the Group 2 claims is being filed concurrently with this response.

Applicant has also made some minor claim amendments to some of the method claims in the elected group. These amendments have been made to more clearly define the relationship between the active and return electrodes and the high frequency voltage source.

Respectfully submitted,

John T. Raffle
Reg. No. 38,585

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Fax No.: 1-703-308-0758
Assistant Commissioner for Patents,
Washington, D.C. 20231,
on

March 25, 1997

TOWNSEND and TOWNSEND and CREW LLP

By Rhonda J. Stine
Rhonda J. Stine

Attorney Docket No. 16238-000700

PATENT

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B
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MAR 25 1997
GROUP 3300

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PHILIP E. EGGERS et al.

Application No.: 08/561,958

Filed: November 22, 1995

For: SYSTEM AND METHOD FOR
ELECTROSURGICAL CUTTING AND
ABLATION

Examiner: MENDEZ, M.

Art Unit: 3306

SUPPLEMENTAL
AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Before action on the merits, please amend the above
identified application as follows.

P 30017 04/14/97 08561958 20-1430 030 204 130.00CH

IN THE SPECIFICATION:

On page 13, line 14, delete the word "using".

On page 18, line 27, delete "voltages" and insert --
voltage--.

On page 21, line 5, between "occurring" and "the
region.." insert --in--, so that it reads --occurring in the
region.---

B

A21471

PATENT

PHILIP B. EGGERS et al.
 Application No.: 08/561,958
 Page 2

On page 22, line 36, delete "current" and insert --
 currents--.

On page 23, line 12, delete the word "laser".

On page 32, line 31, insert --return-- before the word
 "electrode".

IN THE CLAIMS:

Please cancel claims 1-22, 29, 30, 33, 36-38, and 57.
 Please amend claims 23-28, 31, 32, 34, 35, 39-56, 58 and 59 as
 follows. Please add claims 80-105. All claims have been set
 forth for convenience of reference.

Please cancel claims 1-22.

1 25. (Twice Amended) A method for applying energy to a
 2 target site on a patient body structure comprising:
 3 providing an [active] electrode terminal and a return
 4 electrode electrically coupled to a high frequency voltage
 5 source;
 6 positioning the active electrode in close proximity to
 7 the target site in the presence of an electrically conducting
 8 terminal [liquid]; and
 9 applying a high frequency voltage between the [active]
 10 electrode terminal and the return electrode, the high frequency
 11 voltage being sufficient to vaporize the fluid [liquid] in a thin
 12 layer over at least a portion of the [active] electrode terminal
 13 and to induce the discharge of energy to the target site in
 14 contact with [from] the vapor layer.

1 26. (Twice Amended) The method of claim 25 wherein
 2 the [active] electrode terminal comprises an electrode array
 3 including a plurality of isolated electrode terminals.

PHILIP E. EGGERS et al.
Application No.: 08/561,958
Page 3

PATENT

13 25. (Amended) The method of claim 25 wherein [the] at least a portion of the energy induced [from the vapor layer] is in the form of photons having a wavelength in the ultraviolet spectrum.

14 26. (Amended) The method of claim 23 wherein at least a portion of the energy [induced from the vapor layer] is in the form of energetic electrons.

3 27. (Amended) The method of claim 24 wherein the isolated electrode terminals each have a contact surface area in the range of about 0.25 mm² to 50.0 mm² [below 15 mm²].

28. (As Filed) The method of claim 24 wherein the isolated electrode terminals have circular contact surfaces with an area in the range from 0.01 mm² to 1 mm².

Please cancel claims 29 and 30.

5 31. (Amended) The method of claim 24 wherein the electrode terminals are spaced from each other a distance of about 0.0005 to 2.0 [5 to 0.01] mm.

32. (As Filed) The method of claim 24 wherein the electrode array is disposed over a distal tip of an electrosurgical probe.

Please cancel claim 33.

34. (As Filed) The method of claim 24 wherein the electrode terminals comprise a material with a relatively low thermal conductivity.

35. (As Filed) The method of claim 24 wherein the electrode materials comprise a material selected from the group consisting of titanium, tungsten, platinum, aluminum and tantalum.

Please cancel claims 36-38.

PATENT

PHILIP E. EGGERS et al.
Application No.: 08/561,958
Page 4

1 17²⁵. (Amended) The method of claim 23 wherein the high
2 frequency voltage is at least 200 [300] volts peak to peak.

B4 1 18²⁵. (Amended) The method of claim 23 wherein the
2 voltage is in the range from 500 [600] to 1400 volts peak to
3 peak.

B4 1 19²⁵. (Amended) The method of claim 23 wherein the
2 [active] electrode terminal is positioned between 0.02 to 5 mm
3 from the target site.

B5 1 20²⁵. (Amended) The method of claim 23 wherein the
2 vapor layer has a thickness of about 0.02 to 2.0 mm [10 to 400
3 microns].

B6 1 21²⁵. (Twice Amended) The method of claim 23 wherein
2 the distance between the most proximal portion of the [active]
3 electrode terminal [surface] and the most distal portion of the
4 return electrode is [surface] are spaced apart by a distance in
5 the range from 0.5 [1] to 10 mm.

[1 22²⁵. (As Filed) The method of claim 24 wherein the return
2 electrode has a distal end positioned proximal to the electrode array.

B7 1 23²⁵. (Twice Amended) The method of claim 23 wherein
2 the [active] electrode terminal [surface] and the return
3 electrode are of comparable size and comprise a bipolar array of
4 isolated electrode terminals which both come in close proximity
5 or in contact with the body structure.

B6 1 23²⁶. (Amended) The method of claim 23 wherein the
2 liquid phase of the electrically conducting fluid [liquid] has a
3 conductivity greater than 2 mS/cm.

1 24²⁵. (Amended) The method of claim 23 wherein the
2 liquid phase of the electrically conductive fluid [liquid]
3 comprises isotonic saline.

PHILIP E. EGGERS et al.
Application No.: 08/561,958
Page 5

PATENT

1 ²⁸ ~~46~~ (Twice Amended) A method for applying energy to a
2 target site on a patient body structure comprising:
3 providing an [active] electrode terminal and a return
4 electrode electrically coupled to a high frequency voltage
5 source;
6 positioning the [active] electrode terminal in close
7 proximity to the target site in the presence of an electrically
8 conducting fluid [liquid]; and
9 applying a high frequency voltage between the [active]
10 electrode terminal and the return electrode, ~~the~~ high frequency
11 voltage being sufficient to impart sufficient energy into the
12 target site to ablate [several cell layers of] the body structure
13 without causing substantial tissue necrosis below the surface of
14 the body structure underlying the ablated body structure [beyond
15 the several cell layers].

1 ²⁹ ~~48~~ (Amended) The method of claim ~~46~~ ²⁸ wherein the
2 applying step comprises:
3 vaporizing the electrically conducting fluid [liquid]
4 in a thin layer over at least a portion of the [active] electrode
5 terminal [surface]; and
6 inducing the discharge of photons to the target site in
7 contact with [from] the vapor layer.

1 ³⁰ ~~50~~ (Amended) The method of claim ~~48~~ ²⁹ wherein the
2 applying step comprises:
3 vaporizing the electrically conducting fluid [liquid]
4 in a thin layer over at least a portion of the active electrode
5 surface; and
6 inducing the discharge of energetic electrons to the
7 target site in contact with [from] the vapor layer.

1 51. (As Filed) The method of claim 48 wherein the depth of
2 necrosis is 0 to 400 microns.

1 ³¹ ~~52~~ (Twice Amended) A method for applying energy to a
2 target site on a patient body structure comprising:

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3 providing an active electrode and a return electrode
4 electrically coupled to a high frequency voltage source;
5 positioning the [active] electrode terminal in close
6 proximity to the target site in the presence of an electrically
7 conducting fluid [liquid]; and
8 applying a high frequency voltage between the [active]
9 electrode terminal and the return electrode, the high frequency
10 voltage being in the range from 500 [600] to 1400 volts peak to
11 peak.

53. (As Filed) The method of claim 52 wherein the high
frequency voltage is in the range from 700 to 900 volts peak to peak.

1 32 ~~54~~ 54. (Twice Amended) A method for applying energy to a
2 target site on a patient body structure comprising:
3 providing an active electrode electrically coupled to a
4 high frequency voltage source;
5 positioning the [active] electrode terminal in close
6 proximity to the target site in the presence of an electrically
7 conducting fluid [liquid]; and
8 generating a voltage gradient between the [active]
9 electrode terminal and tissue at the target site, the voltage
10 gradient being sufficient to create an electric field that cause
11 the breakdown of [breaks down the] tissue through molecular
12 dissociation or disintegration.

1 33 ~~55~~ 55. (Twice Amended) The method of claim 54 wherein
2 the generating step comprises:
3 providing a return electrode electrically coupled to a
4 high frequency voltage source;
5 applying a high frequency voltage between the [active]
6 electrode terminal and the return electrode; and
7 vaporizing the electrically conducting fluid [liquid]
8 in a thin layer over at least a portion of the [active] electrode
9 terminal [surface].

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PATENT

1 ~~54~~ ⁵⁸ (Amended) The method of claim ~~55~~ ⁵⁸ further
2 comprising developing a film layer of vapor between the active
3 electrode and the body structure [tissue] at the target site.

Please cancel claim 57.

1 ~~55~~ ⁵⁸ (Amended) The method of claim ~~55~~ ⁵⁸ further
2 comprising cooling the tissue with the electrically conducting
3 fluid [liquid] to reduce the temperature rise of those portions
4 of the body structure adjacent the target site [shield the tissue
5 from the high frequency voltage].

1 ~~56~~ ⁵⁹ (Amended) The method of claim ~~58~~ ⁵⁹ wherein the
2 cooling step includes translating the distal surface [tip] of the
3 electrode terminal [probe] over the target site to allow the
4 electrically conducting fluid [liquid] to contact the tissue
5 after the tissue has been subjected to the electric field [high
6 frequency voltage].

Please cancel claims 60-79, as they have been
restricted out.

Please add claims 80-105.

1 ~~25~~ ⁸⁰ (New) The method of claim ~~23~~ ⁸⁰ wherein the
2 electrode height of the most distal portion of the electrode
3 terminal relative to the most proximal portion of the electrode
4 terminal exposed to the electrically conducting fluid is in the
5 range from 0.0 to 2.0 mm.

1 ~~31~~ ⁸¹ (New). The method of claims ~~25~~ ⁸¹ and ~~48~~ ⁸¹ wherein the
2 electrode terminal is surrounded and supported by an insulating
3 matrix at or near the distal tip of the probe to electrically
4 isolate the proximal portion of the electrode terminal from the
5 electrically conductive fluid, the insulating matrix comprising
6 an inorganic material.

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 Application No.: 08/561,958
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38 ~~22~~ 37
 82. (New) The method of claim 81 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

10
 83. (New) The method of claim 24 wherein the electrode height of the most distal portion of any of the electrode terminals relative to the most proximal portion of said electrode terminals exposed to the electrically conducting fluid is in the range from 0.0 to 2.0 mm.

16
 84. (New) The method of claim 24 wherein the electrode terminals are surrounded and supported by an insulating matrix at or near the distal tip of the probe to electrically isolate proximal portions of the electrode terminals from the electrically conductive fluid, the insulating matrix comprising an inorganic material.

12
 85. (New) The method of claim 84 wherein the inorganic material is selected from the group consisting essentially of ceramic, glass and glass/ceramic compositions.

39 ~~22~~ 37
 86. (New) The method of claim 81 wherein the distal surface of the electrode terminal is recessed below the surface of the insulating matrix by a distance from 0.01 mm to 1.0 mm.

40 ~~22~~ 37
 87. (New) The method of claim 81 wherein the distal surface of the electrode terminal is flush with the surface of the insulating matrix.

41 ~~22~~ 37 42
 88. (New) The method of claims 86 and 87 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

42 ~~22~~ 41
 89. (New) The method of claim 88 wherein the generating step comprises:
 providing a return electrode electrically coupled to a higher frequency voltage source;

54

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Application No.: 08/561,958
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5 applying a high frequency voltage between the return
6 electrode and the array of electrode terminals; and
7 vaporizing the electrically conducting fluid in a thin
8 layer over one or more of the electrode terminals of the array.

90. (New) The method of claim ^{43 44} 29 further comprising
developing a film layer of vapor between one or more of the
electrode terminals and the target site.

91. (New) The method of claim ^{43 44} 30 further comprising
cooling the tissue with the electrically conducting fluid to
reduce the temperature rise of those portions of the body
structure adjacent the target site.

92. (New) The method of claim ^{15 14} 31 wherein the energy
of the energetic electrons is sufficient to cause disassociation
or disintegration of molecules of the body structure.

93. (New) The method of claim ^{16 14} 32 wherein the energy
evolved by the energetic electrons is greater than 3eV.

94. (New) The method of claims ^{45 30} 33 and ³⁷ 34 wherein the
density of the vapor layer is less than about 10^{20} atoms/cm³.

95. (New) The method of claims ^{44 31} 35 and ³⁰ 36 wherein the
electrode terminal is configured to promote bubble nucleation
causing the formation of the vapor layer.

96. (New) The method of claims ^{45 32} 37 and ^{28 37} 38 wherein the
electrode terminal has a contact surface area in the range of
about 0.25 mm² to 50 mm².

97. (New) The method of claims ^{48 46} 39 and ^{20 37 30 46} 40 wherein the
high frequency voltage is at least 200 volts peak to peak.

55

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1 49
2 96. (New) The method of claims 46 and 52 wherein the
3 high frequency voltage is in the range from about 500 to 1400
volts peak to peak.

1 50 76
2 97. (New) The method of claims 46 and 52 wherein the
3 electrode terminal is positioned between 0.02 to 2.0 mm from the
target site.

1 51 49
2 100. (New) The method of claims 46 and 52 wherein the
3 electrode terminal and the return electrodes comprise a bipolar
array of isolated electrode terminals.

1 52 23
2 101. (New) The method of claims 23 and 48 further
3 comprising cooling the tissue with the electrically conducting
4 fluid to reduce the temperature rise of those portions of the
5 body structure adjacent the target site.

1 53 74
2 102. (New) The method of claim 101 wherein the cooling
3 step includes translating the distal surface of the active
4 electrode over the target site to allow the electrically
5 conducting fluid to contact the tissue after the tissue has been
subjected to the electric field.

1 54 36
2 103. (New) The method of claims 23 and 48 further
3 comprising evacuating fluid generated at the target site with a
4 suction lumen having a distal end adjacent the electrode
terminal.

1 55 36
2 104. (New) The method of claims 23 and 48 wherein the
3 target site is a tumor within or on the patient's body.

1 56 34
2 105. (New) The method of claims 46 and 52 wherein
3 the electrode terminal comprises an electrode array including a
plurality of isolated electrode terminals.--

MAR. 25. 1997 8:35AM

NO. 072 P. 15

PATENT

PHILIP E. EGGERS et al.
Application No.: 08/561,958
Page 11

REMARKS

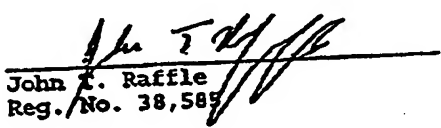
Claims 23-105 are pending.

Applicants have cancelled claims 1-22 and 29, 30, 33, 36-38 and 57, and prepared a few minor amendments to the remainder of the claims. In addition, dependent claims 80-105 have been added to further claim the features of the present invention. Applicants note that these features are fully described in the present invention and no new matter has been entered.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 326-2400.

Respectfully submitted,


John T. Raffle
Reg. No. 38,585

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
(415) 326-2400
Fax (415) 326-2422
JTR:rjs
BATE1403970070000077.AMD

A 21482

Commissioner of Patents and Trademarks
Washington, D.C. 20231, on Dec. 17, 1997

By Walter J. Jones

PATENTED MAY 27 1908

PATENT

Attorney Docket No. 16238-000700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPROVED
AS INDICATE

In re Patent of:

PHILIP E. EGGERS et al.

01/14/1998 SPENDING REPORT 12 : 5,697,882
01 FEB 1998 100.00 00

Issue Date: December 16, 1997

For: SYSTEM AND METHODS FOR
ELECTROSURGICAL CUTTING AND
ABLATION

**REQUEST FOR
CERTIFICATE OF CORRECTION
UNDER 37 CFR §1.323**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Pursuant under 37 CFR §1.323, Applicant submits a Certificate of Correction amending claim 23. These amendments to claim 23 have been made to correct typographical errors that were made in Applicant's Amendment filed on March 25, 1997. During that amendment, Applicant amended all of the claims to replace the term "liquid" with "fluid". In addition, Applicant amended all of the claims to replace the term "active electrode" with "electrode terminal".

In claim 23, however, Applicant mistakenly forgot to replace the term "active electrode" with "electrode terminal" on line 5. This term on line 5 derives antecedent basis from "an electrode terminal" on line 3 (also note the reference to electrode terminal on lines 7 and 9 of claim 23). Accordingly, in order to correct this error in antecedent basis, Applicant wishes to change "active electrode" on line 5 to "electrode terminal".

Patent No. 5,697,882
Philip E. Eggers et al.
Page 2

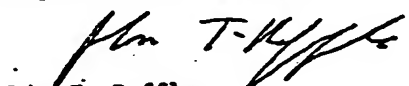
Similarly, on line 6 of claim 23, Applicant replaced "liquid" with "terminal" instead of replacing it with "fluid" as in the rest of claim 23, and the rest of the claims. In particular, note line 8 of claim 23 which refers to the fluid, clearly deriving antecedent basis from an earlier recitation of "fluid" in the claim. This antecedent basis must come from line 6. In addition, note dependent claims 46 and 47, which also refer to the electrically conductive fluid. These claims depend from claim 23. Finally, Applicant points out that the rest of the independent claims in this application (Claims 48, 52 and 54) were amended to recite the step of "positioning the electrode terminal in close proximity to the target site in the presence of an electrically conducting [liquid] fluid".

Accordingly, it should clearly be seen that the above changes merely correct typographical errors made by the Applicant during prosecution of this case.

The desired corrections are set forth on form PTO 1050, enclosed herewith.

Enclosed is a check in the amount of \$100.00, pursuant to 37 CFR \$1.20(a).

Respectfully submitted,


John T. Raffle
Reg. No. 38,585

ArthroCare Corporation
595 N. Pastoria Avenue
Sunnyvale, California 94086
(408) 736-0224

A 21507

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

IN THE CLAIMS:

23. A method for applying energy to a target site on a patient body structure comprising:
providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
positioning the [active] electrode terminal in close proximity to the target site in the presence of an electrically conducting [terminal] fluid; and
applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Mailing address of sender:

John T. Raffle
ARTHROCARE CORPORATION
595 N. Pastoria Avenue
Sunnyvale, California 94086

Patent No. 5,697,882

No. of add'l. copies
@ 50¢ per page
→ 0

PTO Form 1050 (modified); Atty Docket No.: 16238-000700

A 21508

NOTICE RE: CERTIFICATES OF CORRECTION

#1

DATE : 2-2-98

TO : Supervisor, Art Unit Mendez 3308

SUBJECT: Certificate of Correction Request in Patent No. 5697882

A response to the following question(s) is requested with respect to the accompanying request for a certificate of correction.

- ☒ 1. Would the change(s) requested under 37 CFR 1.323 constitute new matter or require reexamination of the application?
- ☒ 2. Would the change(s) requested under 37 CFR 1.323 materially affect the scope or meaning of the claims allowed by the examiner in the patent?
- ☐ 3. Applicant disagrees with change(s) initialed and dated by Examiner in lieu of an Examiner's Amendment. Should the change request be granted?
- ☐ 4. With respect to the change(s) requested, correcting Office errors, should the patent read as shown in the certificate of correction?
- ☐ 5. If the amendment filed _____ had been considered by the Examiner, would the amendment have been entered?

PLEASE RESPOND WITHIN 7 DAYS AND RETURN THE FILE TO Room 918, PK III

Franklin Fisher

Legal Instrument Examiner

RUSH

TO: CERTIFICATE OF CORRECTION BRANCH

DATE:

The decision regarding the change(s) requested in the certificate of correction is shown below.

- | | | |
|---------------------------------|--|---|
| <input type="checkbox"/> 1. YES | <input checked="" type="checkbox"/> NO | <input type="checkbox"/> Comments below |
| <input type="checkbox"/> 2. YES | <input checked="" type="checkbox"/> NO | <input type="checkbox"/> Comments below |
| <input type="checkbox"/> 3. YES | <input type="checkbox"/> NO | <input type="checkbox"/> Comments below |
| <input type="checkbox"/> 4. YES | <input type="checkbox"/> NO | <input type="checkbox"/> Comments below |
| <input type="checkbox"/> 5. YES | <input type="checkbox"/> NO | <input type="checkbox"/> Comments below |

☐ Comments NO COMMENTS NECESSARY

[Signature]
Supervisor

2/7/98

3306

Art Unit

PTOL-306 (REV 10-77)

U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office

A 21509

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,697,882
DATED : December 16, 1997
INVENTOR(S) : Philip E. Eggers et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

- ✓ 52. The method of claims 23 or 48 further comprising cooling the tissue with the electrically conducting fluid to reduce the temperature rise of those portions of the body structure adjacent the target site.
- ✓ 54. The method of claims 23 or 48 further comprising evacuating fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal.
- ✓ 55. The method of claims 23 or 48 wherein the target site is a tumor within or on the patient's body.
- ✓ 56. The method of claims 48 or 52 wherein the electrode terminal comprises an electrode array including a plurality of isolated electrode terminals.

Mailing address of sender:

John T. Raffle
ARTHROCARE CORPORATION
595 N. Pastoria Avenue
Sunnyvale, California 94086

Patent No. 5,697,882

No. of add'l. copies
@ 50¢ per page
→ 0

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
90/005,601	12/30/99	604	3762	
APPLICANT 5697536, ARTEROCARE CORPORATION, SURGICAL, CA.				
CONTINUING DOMESTIC DATA VERIFIED THIS APPLN IS A REI OF 08/746,000 11/18/96 PAT 5,697,836 WHICH IS A DIV OF 06/465,219 06/07/95 PAT 5,697,301 WHICH IS A CIP OF 06/446,767 06/02/95 PAT 5,697,909 WHICH IS A CIP OF 06/059,681 05/10/93 ABN WHICH IS A CIP OF 07/958,977 10/09/92 PAT 5,366,443 WHICH IS A CIP OF 07/817,576 01/07/92 ABN				
INT'L (MUT'L STAGE) DATA VERIFIED				
FOREIGN APPLICATIONS VERIFIED				
IF REQUIRED, FOREIGN FILING LICENSE GRANTED 01/05/00				
For an Priority claimed 35 USC 118 (a)-(4) conditions met		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not after Allowance		STATE OF COUNTRY
Verified and Acknowledged: _____ EXHIBIT 1		SHEETS DRAWING 0		TOTAL CLAIMS 44
ADDRESS JAMES M. HESLIN TOWNSEND AND TOWNSEND AND CREW 20TH FLOOR STEWART STREET TWR ONE MARKET PLACE SAN FRANCISCO CA 94105-1492		TITLE SYSTEM AND METHOD FOR ELECTROSURGICAL CUTTING AND ABLATION		
FILING FEE RECEIVED \$2,620	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.10 Fee (Filing) <input type="checkbox"/> 1.17 Fee (Processing Ext. of time) <input type="checkbox"/> 1.19 Fee (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit	

Plaintiff
Trial Exhi
PX 7
C.A.N. 94-004-01

A 21666

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No. : 5,697,536

Prior Examiner:
Manuel Mendez

Date of Issue : December 16, 1997

Name of Patentee : Eggers et al.

Title of Invention : SYSTEM AND METHOD FOR ELECTROSURGICAL
CUTTING AND ABLATION

REEXAMINATION REQUEST

Commissioner of Patents
and Trademarks
Box REEXAM
Washington, D.C. 20231

CERTIFICATE UNDER 37 CFR 1.8: The Undersigned hereby certifies that this paper or papers, as described herein below, are being deposited with the United States Postal Service, on the date shown below with sufficient postage as first class mail in an envelope addressed to the:

Commissioner of Patents and Trademarks
Box REEXAM
Washington, D.C. 20231

On this 23rd day of December, 1999.

By:

William C. Fuss
William C. Fuss
Reg. No. 30,054

Dear Sir:

Reexamination is requested pursuant to 35 U.S.C. §§302-307 and 37 CFR §1.510 of the above-identified patent. The following items are enclosed.

1. Prior art relied upon and a Form PTO-1449 (37 CFR §1.510 (b) (3)).
2. A substantial new question of patentability raised by the above prior art and the pertinency of the cited prior art of the claims for which reexamination is requested is set forth in the attached STATEMENT OF NEW QUESTION OF PATENTABILITY (37 CFR §§1.510 (b) (1) and (2)).
3. A cut-up copy of the original patent showing single columns of the patent reproduced on one side of a separate paper (37 CFR §1.510 (b) (4)).
4. The signature below certified that:

A copy of this request and all accompanying papers has been served on the patent owner at the address provided for in 37 CFR §1.33(c) by depositing the documents in an

envelope bearing first class postage in an official U.S. Postal Service repository at the date set forth below addressed as follows:

Name Hira V. Thapliyal
Arthrocare Corporation

Address 595 North Pastoria Avenue
Sunnyvale, California 94086

5. A check in the amount of \$2,520.00 is attached. (37 CFR §§1.20(c) and 1.510(a)).

Please charge any deficiency to Deposit Account No. _____.

Any refund should be made by check.

The name and address of the person making this request is:

Name William C. Fuess
Reg. No. 30,054

Address FUESS & DAVIDENAS
10951 Sorrento Valley Road
Suite II-G
San Diego, CA 92121-1613

Tel. No.: (858) 452-8293
Facsimile No. (858) 452-6035
E-mail: fuess@funtv.com

Please address all future correspondence as follows:

William C. Fuess
FUESS & DAVIDENAS
10951 Sorrento Valley Road
Suite II-G
San Diego, CA 92121-1613

Respectfully submitted,

Dated: 12/23/99
December 23, 1999

William C. Fuess
William C. Fuess
Reg. No. 30,054

3A

00005601.123099
00005601.123099

STATEMENT OF NEW QUESTION OF PATENTABILITY

I. Patent and Claims for which Reexamination is Requested

Reexamination under 35 U.S.C. §§302-307 and 37 CFR §1.510 is requested of U.S. Patent No. 5,697,536 which issued on December 16, 1997 to Eggers et al., and is assigned to Arthrocare Corporation (hereinafter "the Eggers '536 Patent"). Reexamination is requested of claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 & 63, in view of U.S. Patent No. 4,116,198 to Roos (hereinafter "the Roos '198 Patent"). It is noted that the Roos '198 Patent was not before the Examiner during the prosecution of the Eggers '536 Patent.

II. Statement of Substantial New Question of Patentability

A. Overview

The Eggers '536 Patent is directed to devices employing high frequency voltage to cut and ablate tissue. (Eggers '536 1:19-21).

The Eggers '536 Patent discloses and claims electrosurgical devices that are designed and intended to be used in conductive fluids such as isotonic saline. The electrosurgical device generally includes a current supplying radio frequency generator; an active electrode, or an electrode terminal, mounted near the tip of a surgical probe; a return electrode positioned rearward of and in a spaced apart condition from said active electrode; an insulator separating the active and return electrodes; and, an



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/005,601	DECEMBER 30, 1999	5,697,536	16238-00610

ARTHROCARE CORPORATION
680 VAQUEROS AVENUE
SUNNYVALE CA 94085-3523

EXAMINER

ART UNIT

PAPER

MENDEZ, M. 13

DATE MAILED: NOVEMBER 15, 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

205111-10990006

cc: William C. Fuess, 3rd party.
attorney

Office Action in Ex Parte Reexamination	Control No. 80/005,601	Patent Under Reexamination	
	Examiner Manuel Mendez	Art Unit 3763	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

- a ☒ Responsive to the communication(s) filed on 19 June 2002. b ☐ This action is made FINAL.
 c ☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 (Two) month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an ex parte reexamination certificate in accordance with this action. 37 CFR 1.550(d). EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c). If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 3. <input type="checkbox"/> Interview Summary, PTO-474. |
| 2. <input type="checkbox"/> Information Disclosure Statement, PTO-1449. | 4. <input checked="" type="checkbox"/> <u>See Continuation Sheet.</u> |

Part II SUMMARY OF ACTION

- 1a. ☒ Claims 1-61 are subject to reexamination.
 1b. ☐ Claims _____ are not subject to reexamination.
☐ Claims _____ have been canceled in the present reexamination proceeding.
☐ Claims _____ are patentable and/or confirmed.
☒ Claims 1-61 are rejected.
☐ Claims _____ are objected to.
☐ The drawings, filed on _____ are acceptable.
☐ The proposed drawing correction, filed on _____ has been (7a) ☐ approved (7b) ☐ disapproved.
☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some c) ☐ None of the certified copies have
 1 ☐ been received.
 2 ☐ not been received.
 3 ☐ been filed in Application No. _____.
 4 ☐ been filed in reexamination Control No. _____.
 5 ☐ been received by the International Bureau in PCT application No. _____.
 * See the attached detailed Office action for a list of the certified copies not received.
 9. ☐ Since the proceeding appears to be in condition for issuance of an ex parte reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1835 C.D. 11, 453 O.G. 213.
 10. ☐ Other: _____

cc: Requester (if third party requester)
 U.S. Patent and Trademark Office
 PTO-456 (Rev. 04-01)

Office Action in Ex Parte Reexamination

Part of Paper No. 13

DETAILED ACTION

Introduction

The prosecution of Reexamination No. 90/005,601 originated with the filing of a Reexamination Request on December 30, 1999. The Request indicated that the requester considered claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60, and 63, of Eggers, et al., U.S. Patent Number 5,697,536, referenced hereafter as Eggers '536, as being anticipated by Roos, U.S. Patent Number 4,116,198, referenced hereafter as Roos '198. After a complete review of the merits of the Request, the examiner of record concluded that Roos '198 raised a substantial question of patentability. Consequently, an order granting the Request for Reexamination was mailed on February 2, 2000. The order was mailed for a second time on October 27, 2000.

The arguments presented by the Request concerning Roos '198 were addressed in a final decision by the examiner of record and reviewed by a board of primary examiners that convened to analyze the decision and make a final determination. However, before the mailing of the written decision, a new Information Disclosure Statement (IDS) was timely received on June 19, 2002. The IDS comprises of evidentiary documents pertinent to pending litigation at the United States District Court in the State of Delaware (Arthrocare Suit-Delaware, USDC-D. DEL. C.A. No. 01-504-SLR).

In view of the new documents submitted by the IDS, the examiner of record has decided to divide this prosecution in two sections. The first section addresses the issues originally presented by the Request concerning Roos '198 and summarizes the patentability conclusion as it was decided by the examiner of record prior to the receipt of the new IDS. Finally, the second section addresses new relevant references as listed in the IDS received on June 19, 2002, and more specifically, the Supplemental Invalidity Response included in the submitted IDS package.

Section I: Analysis of the Roos Patent

After careful consideration and review of Roos '198, it is hereby found that Roos '198 does not anticipate or render obvious any of the independent claims of record for a variety of reasons that will be discussed below.

Interpretation of the Preamble

The preamble of claim 1, discloses "an electrosurgical system for use with a high frequency power supply and an electrically conducting fluid supply". It is noted that whether a preamble constitutes a limitation to a claim is a matter to be determined by the facts of each case in view of the claimed invention as a whole. See, In re Stencel, 828 F.2d 751, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987). Additionally, the preamble of a claim does not limit the scope of the claim when it merely states intended use of the invention. In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974). However, terms in a preamble are construed as limitations when they give life and

Application/Control Number: 90/005,601
Art Unit: 3763

meaning to the invention claimed. Gerber Garment Technology, Inc. v. Lectra Syst., Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (quoting) Perkins-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 896, 221 USPQ 669, 675 (Fed. Cir.), cert. Denied, 469 U.S. 857 (1984). Although no "litmus test" exists as to what effect should be accorded to terms appearing in a preamble, a patent application in its entirety should be reviewed to determine whether the inventors intended such language to represent additional limitations or mere introductory language. See, e.g., In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673-74 (Fed. Cir. 1994) (Citing Coming Glass Works v. Saitomo Elect. U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed Cir. 1989).

Accordingly, a review of the specification in Eggers '536, reveals in column 4, lines 63-67, that figure 1 is a perspective view of the electro surgical probe, an electrically conducting liquid supply and an electro surgical power supply. Electrically conducting liquid (50) is shown in figure 1, within an IV bag and in fluid communication with the electro surgical probe (10) as shown in figures 2A and 2B. Moreover, in column 12, lines 26-28, the specification states that electrically conducting liquid (50) (e.g., isotonic saline) is caused to flow along the fluid paths (83).

In view of the foregoing, the phrase "an electrically conducting fluid supply" in the preamble of claim 1, must be interpreted in view of the specification as a limitation disclosing a medical container (e.g., IV bag) that stores electrically conducting liquid

(50) such as isotonic saline. The medical container is in fluid communication with the probe (10) allowing the electrically conducting liquid to make contact with the electrodes at the distal end of the probe (10). Additionally, in the last portion of claim 1, the phrase "the fluid path having an inlet adapted to be fluidly coupled to the electrically conductive fluid supply" unequivocally suggests that the drafter intended the preamble phrase "an electrically conducting fluid supply" to be a structural limitation. Clearly, the phrase "an electrically conducting fluid supply" gives life and meaning to the invention claimed, and therefore, must be considered in the assessment of patentability of claim 1.

Assessment of Patentability

205111-10950006
The Roos '198 Patent never describes the use of "electrically conductive fluid" during electrosurgery. The Roos '198 Patent only discloses the use of an unspecified "washing liquid" that flows through the endoscope that houses the treatment and neutral electrodes. See Roos '198 Patent at 4:51-57, Fig. 1. The Roos '198 Patent does not state that the "washing liquid" that is supplied to the region of the surgical site is electrically conductive fluid. This omission is significant, because numerous non-conductive washing liquids, such as distilled water, glycine, sorbitol, and the like, have been used in electrosurgery and are still in use today. See, e.g., U.S. Patent No. 4,936,301 to Rexroth, et al. at 1:62-64 and 2:4-7.

In fact, the Roos '198 specification makes clear that the "washing liquid" delivered to the surgical site in the Roos '198 Patent is not electrically conductive. The

Roos '198 Patent states at column 6, lines 51-53 that "the neutral electrode 11 in the form of a steel band rests on the tissue in large area form, so that good electrical contact is ensured." If the "washing liquid" was electrically conductive, there would be no need for the neutral electrode to rest on the tissue in large area form to ensure good electrical contact. Electrical contact between the neutral electrode and the cutting electrode would be ensured by the "washing liquid" itself. The statement in the Roos '198 Patent that tissue contact with the neutral electrode is needed to ensure electrical contact plainly shows that the "washing liquid" described in the Roos '198 Patent could not have been electrically conductive.

90005601-1.1.1502

A later-issued patent to the same named inventor, U.S. Patent No. 4,706,667, referenced hereafter as Roos '667, demonstrates unequivocally that the "washing liquid" disclosed in the Roos '198 Patent was not electrically conductive. The Roos '198 Patent claims priority to German Patent Application No. 2521719, referenced hereafter as "German Patent Application". The Roos '667 Patent explains at column 1 lines 14-29 that the device described in the German Patent Application (and thus in the Roos '198 Patent) did not work to cut tissue because the medium in contact with the electrodes was not electrically conductive:

"In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or

by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for trouble free cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes".

205X11-10950006
According to the Roos '667 Patent, the device disclosed in the parent application to the Roos '198 Patent (and thus in the Roos '198 Patent itself) did not work because there was insufficient electrical contact between the neutral and cutting electrodes to cut tissue, even though the electrodes were in the "immediate vicinity" of one another. If the Roos '198 Patent had delivered electrically conducting fluid to the tissue site, such as isotonic saline, then the Roos '667 Patent surely would not have stated, as it did, that the cutting and neutral electrodes "only enter into electrical contact" with each other "via the secretion which is present during the cutting process." If Roos '198 had delivered electrically conducting fluid to the tissue site, there would have been an electrical connection between the cutting and neutral electrodes by virtue of the electrically conducting fluid itself, regardless of whether bodily secretions were present. Plainly, Roos '198 used non-conducting "washing liquid" and attempted to rely on bodily secretions from the cutting process to make the non-conductive "washing liquid" more

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conductive. According to the Roos '667 Patent, these secretions did not make the non-conductive "washing liquid" electrically conductive.

Significantly, the Roos '667 Patent did not solve the electrical contact problem described in the Roos '198 Patent by introducing electrically conducting fluid to the tissue site. Rather, the Roos '667 Patent solved the problem of poor conductivity by disclosing a device in which both the cutting and neutral electrodes were in physical contact with the tissue so that current could flow from the cutting electrode, through the tissue, and to the return electrode, not through electrically conducting fluid. The Roos '667 Patent explains at column 4, line 30:

90005601.1:1502
"The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small funnel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral electrode 11".

In conclusion, because the Roos '198 Patent does not disclose or enable electrosurgical ablation in the presence of electrically conductive fluid, it cannot anticipate claims 1, 45, and 63, containing such an element PPG Indus., Inc. v.

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Art Unit: 3763

Page 9

Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.").

Section II: References disclosed in the IDS dated June 19, 2002

Claim Rejections

In order to expedite the prosecution of this reexamination, the examiner of record will make direct references to the Supplemental Invalidity Response (Arthrocare Suit- Delaware, USDC-D. DEL.-C.A. No. 01-504-SLR) submitted with the IDS package dated June 19, 2002.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: ASSISTANT COMMISSIONER FOR PATENTS

Washington, D.C. 20231

APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/005,601	DECEMBER 30, 1999	5,697,536	16238-00610

ARTHROCARE CORPORATION
680 VAQUEROS AVENUE
SUNNYVALE, CA 94085-3523

EXAMINER

MENDEZ, M.

ART UNIT	PAPER
----------	-------

3763

18

DATE MAILED: MARCH 14, 2003 *AK*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

cc: William C. Fuess, 3rd party
attorney

563

PTO-90C (Rev. 3-98)

A 22232

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination	
	Examiner	Art Unit	
	Manuel Mendez	3763	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

1. ☒ Prosecution on the merits is (or remains) closed in this ex parte reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. Cf. 37 CFR 1.313(e). A Certificate will be issued in view of
 - (a) ☒ Patent owner's communication(s) filed: 18 December 2002
 - (b) ☐ Patent owner's late response filed: _____
 - (c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____
 - (d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 1.182).
 - (e) ☐ Other: _____
- Status of Ex Parte Reexamination:

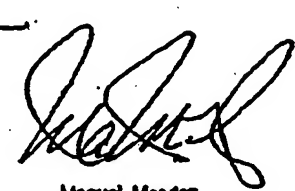
(f) Change in the Specification: ☐ Yes, ☐ No

(g) Change in the Drawing: ☐ Yes, ☐ No

(h) Status of the Claim(s):

 - (1) Patent claim(s) confirmed: 1-64
 - (2) Patent claim(s) amended (including dependent on amended claim(s)): _____
 - (3) Patent claim(s) cancelled: _____
 - (4) Newly presented claim(s) patentable: _____
 - (5) Newly presented cancelled claim: _____
2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."
3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).
4. ☒ Note attached LIST OF REFERENCES CITED (PTO-1449).
5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.
6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have
 - ☐ been received,
 - ☐ not been received,
 - ☐ been filed in Application No. _____,
 - ☐ been filed in reexamination Control No. _____,
 - ☐ been received by the International Bureau in PCT Application No. _____.

* Certified copies not received: _____
7. ☐ Note attached Examiner's Amendment.
8. ☐ Note attached Interview Summary (PTO-474)
9. ☐ Other: _____


 Manuel Mendez
 Primary Examiner
 Art Unit 3763

cc: Requester (if third party requester)

REEXAMINATION OF U.S. PATENT NUMBER 5,697,536

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

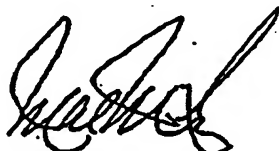
The examiner of record concurs with the arguments presented by the patent owner on paper number 15. Accordingly, it is concluded that claims 1-64 are allowable over the prior art of record.

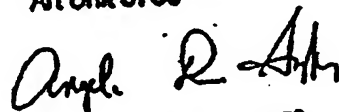
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3763

March 4, 2003


Manuel Mendez
Primary Examiner
Art Unit 3763

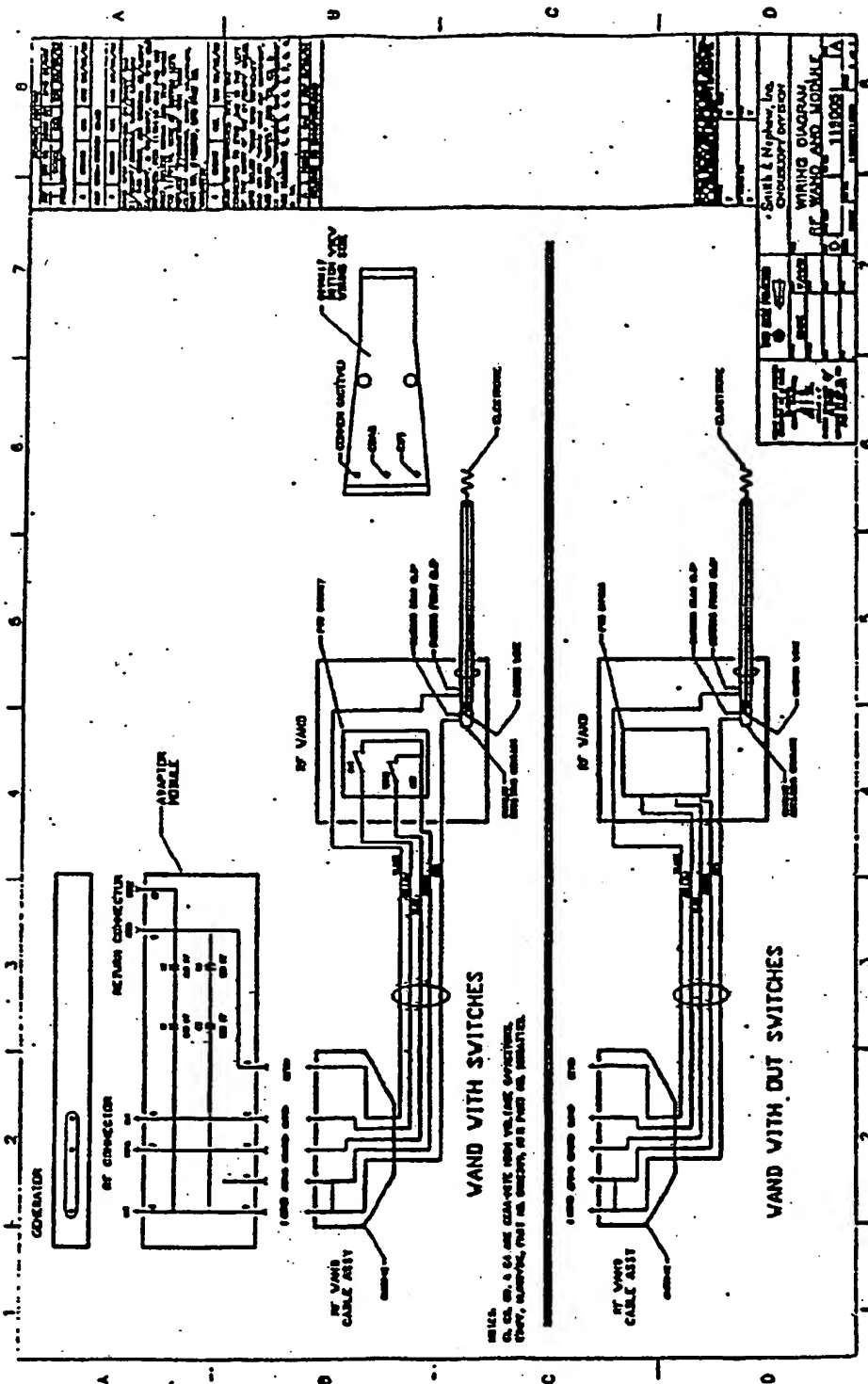

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

FORM PTO-1449 (Modified)		Attorney Docket No. 16238-000610		Patent No.: 5,697,536		
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: PHILIP B. EGGERS et al.				
		Issue Date: December 16, 1997		Group:		
Reference Designation U.S. PATENT DOCUMENTS						
Examiner Initial	Document No.	Date	Name	Class	Sub- class	Filing Date
AA						
AB						
AC						
AD						
AE						
AF						
FOREIGN PATENT DOCUMENTS						
						Translation (yes/no)
AG						
AH						
AI						
OTHER ART. (Including Author, Title, Date, Pertinent Pages, Etc.)						
AJ	Correspondence from C. Larson Dept. of Health & Human Services dated April 22, 1991 (3pgs)					
AK	Summary of Safety and Effective Information (2pgs)					
AL	Correspondence from R. Britain Dept. of Health & Human Services dated August 12, 1985					
AM	Correspondence from J. Malis Valley Forge dated July 25, 1985 (3pgs)					
AN	L. Malis J. Neurosurg. Vol. 85, pp. 970-975 (1996).					
AO	Excerpt from seminar by L. Malis, MD 1995 American Assoc. of Neurological Surgeons Meeting (1pg)					
AP	L. Malis The Value of Irrigation During Bipolar Coagulation (1pg)					
AQ	L. Malis New Trends in Microsurgery and Applied Technology (pgs 9-16)					
AR	Codman Bipolar Electrosurgery Products brochure (8 pgs)					
AS	The MALIS Bipolar Coagulating and Bipolar Cutting System CMC-II brochure (2pgs)					
AT	"Valley Forge's new products" Clinica Vol. 475, p. 8 (1991)					
AU	The MALIS Bipolar Electrosurgical Systems CMC-II (Catalog 80-1170) 14 pgs					
EXAMINER	DATE CONSIDERED		FEBRUARY 25, 2003			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

This appendix designation corresponds to a video admitted at trial as exhibit PX – 105.

PX – 105 is reproduced on a CD-ROM located in a pocket envelope at the end of Volume 1 of this Appendix.

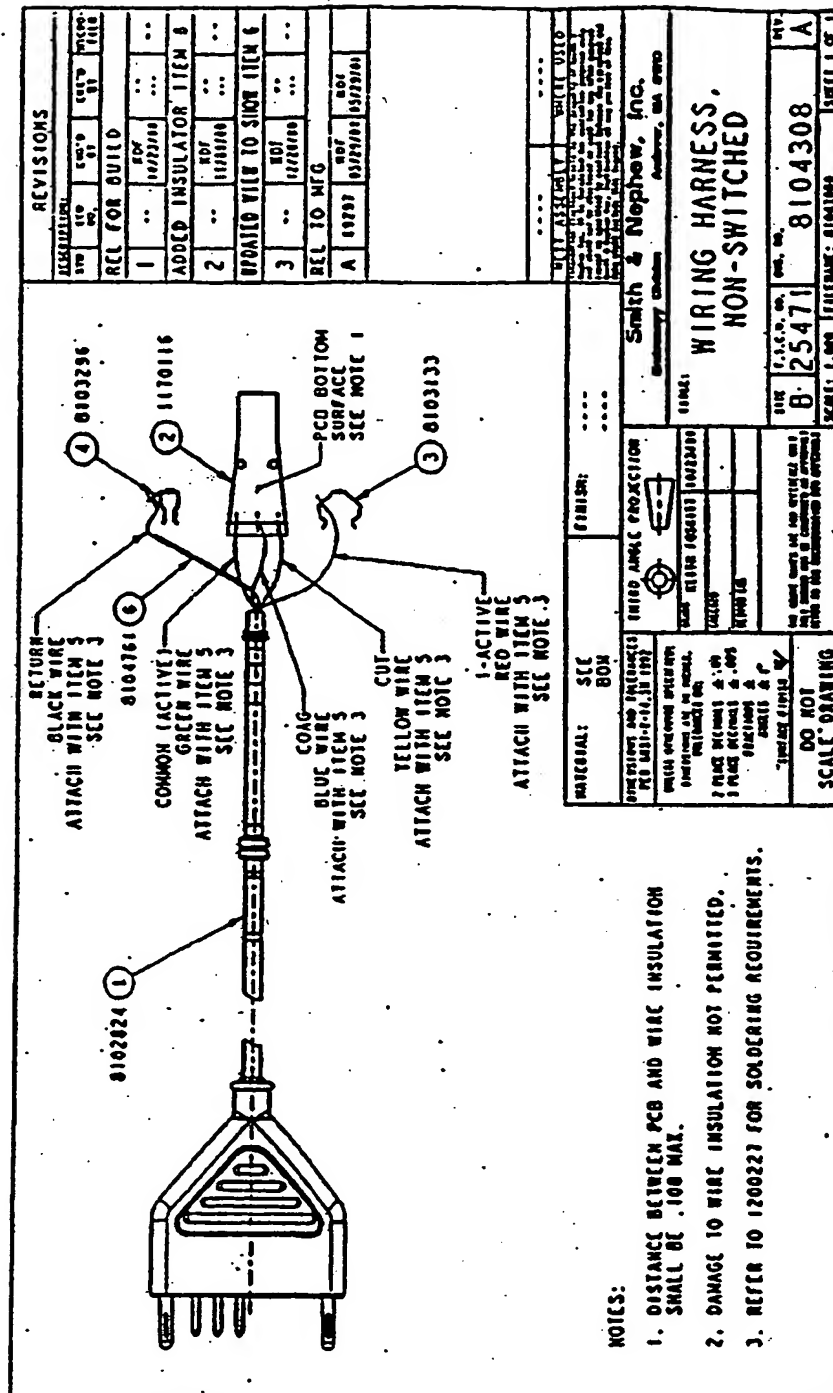


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PX 107A

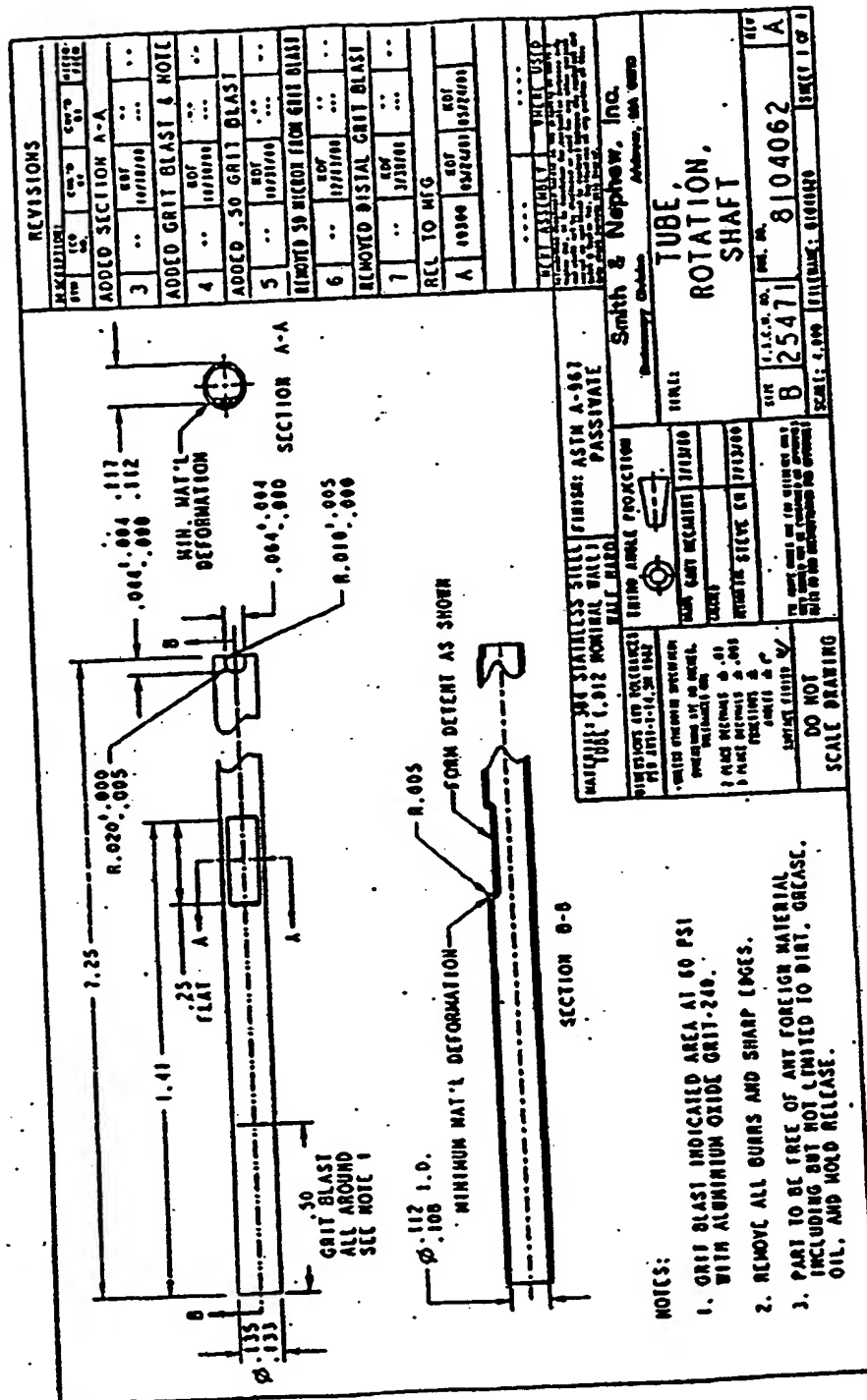
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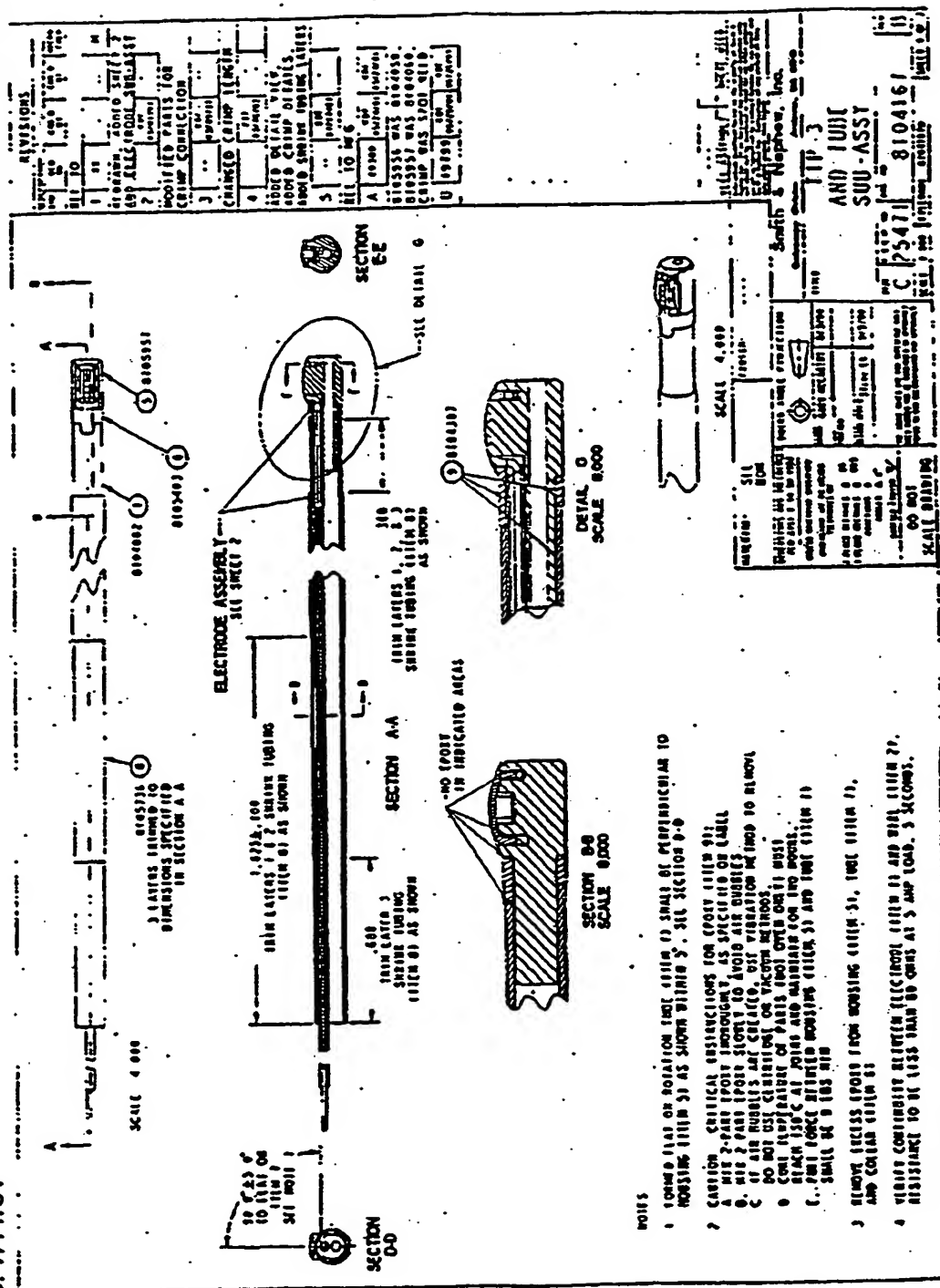
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Smith+Nephew

Dyonics® Series 9000 ElectroBlade™ Resector

Instructions for Use



INDICATIONS

The Dyonics ElectroBlade Series 9000 Resector is indicated in arthroscopic surgical procedures of large and small articular cavities for resection and excision of soft tissues. The Dyonics ElectroBlade Resector is effective in tissue resection and hemostasis of bleeding vessels. It is intended for arthroscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as an irrigant under direct or video-assisted fiber optic visualization.

CONTRAINDICATIONS

- Use of the Dyonics ElectroBlade Resector is contraindicated in any non-arthroscopic surgical procedure and in procedures where saline and Ringer's lactate is not used as an irrigant.
- The Dyonics ElectroBlade Resector is contraindicated in neurosurgery and cardiovascular surgery.
- The Dyonics ElectroBlade Resector is also contraindicated for use with generators not indicated in the Instructions for Use.
- The Dyonics ElectroBlade Resector is not appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason.
- Use of the Dyonics ElectroBlade Resector is contraindicated in patients with heart pacemakers or other electronic device implants.
- The Dyonics ElectroBlade Resector should not be used in patients exhibiting ankylosis, without adequate joint space or distortion for arthroscopic inspection. Abrasion arthroplasty may not be effective in treating heavy patients or those with ankylosis, instability, or expectations beyond the relief of pain.
- Intracortical abrasion arthroplasty may be contraindicated in patients not qualifying for high tibial osteotomy or total knee replacement.
- Synovectomy is contraindicated when disease has progressed beyond the phase of synovial proliferation, and in cases of advanced rheumatoid arthritis when erosion of the articular cartilage is present.

IMPORTANT

- The Dyonics ElectroBlade Resector is compatible with type "B" MDU (motor drive unit) and type "CF" Valleylab Electrosurgical Generators: Force FX, Force FX-C, and Force 2.
- The Dyonics ElectroBlade Resector is preassembled, packaged sterile and ready for use. Any attempt to disassemble the Dyonics ElectroBlade Resector cables will damage them and make them unusable.
- To remove a Dyonics ElectroBlade Resector from its sterile package, peel the Tyvek® seal off the blade tray. Sterility is guaranteed if package has not been opened or damaged.
- Do not put the electrosurgical generator on the Smith & Nephew shaver system cart.

READ THE DYONICS SHAVER SYSTEMS' OPERATIONS/ SERVICE MANUALS, THE GENERATOR MANUFACTURER'S OPERATIONS MANUAL, AND ANY ASSOCIATED EQUIPMENT OPERATIONS MANUALS FOR SYSTEM SETUP, OPERATION AND CLEANING INSTRUCTIONS.

WARNINGS

- Do not touch the open window area at the tip of the shaver blade when power from the electrosurgical generator is being applied. Electrical injury may result.
- The Dyonics ElectroBlade Resector is offered as a single-use sterile disposable device. Do not reuse. Attempts to reuse these devices may damage the insulative coating or cable resulting in harm to the patient or user.
- Do not activate the Dyonics ElectroBlade Resector when the tip is in contact with or in close proximity to a metal cannula. Arcing to a metal cannula may cause a patient burn.
- Do not withdraw the Dyonics ElectroBlade Resector while power from the electrosurgical generator is being applied.
- Do not lay any electrosurgical instrument on the patient or drapes. If another electrosurgical instrument of any type, whether foot or hand controlled is activated, both devices will be activated and may result in patient burns.
- Failure of the RF surgical equipment could result in an unintended increase in power output.
- During RF activation, use arthroscopic visualization to ensure that suction is on and the shaver blade tip and the uninsulated tube return are completely surrounded by irrigant solution. Ensure that there is an uninterrupted flow of irrigant through the blade.
- Do not wrap the cables around metal objects. Wrapping the cable around metal objects may induce currents that could lead to shock, fire, or injury to the patient or surgical personnel.
- It is recommended that RF activation of the Dyonics ElectroBlade Resector be applied in brief intervals to minimize the potential for collateral tissue damage associated with the use of RF energy.
- As with all electrosurgical devices, do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide or oxygen. An electrosurgical device has the potential for providing a source for ignition. Endogenous gases, which accumulate in body cavities, can also be a source of ignition.
- The electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- The patient should not come into contact with metal parts which are grounded or which have appreciable capacitance to ground (i.e., operating table supports). The use of anti-static sheeting is recommended for this purpose.

DYONICS®

Plaintiff's
Trial Exhibit
PX 189

SN 0046676

A 22613

Smith & Nephew Inc.
Endoscopy Division

Dyonics® Series 9000
ElectroBlade™ Resector

Clinical Evaluation Summary

Prepared by:

Dianne DeLucia

Dianne DeLucia
Clinical Research Associate II

3/12/02
Date

Reviewed by:

Karen Drucker

Karen Drucker
Project Leader

3-12-02
Date

Jason B. Krieser

Jason Krieser
Domestic Market Manager

3/11/02
Date

Steve Keene

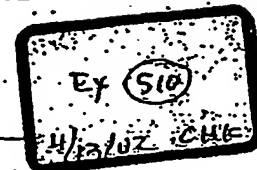
Steve Keene
International Market Manager

3/12/02
Date

Tedd Gosian

Tedd Gosian
Clinical Research Manager

12-Mar-02
Date



SN 0050063

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Dyonics® Series 9000 ElectroBlade™ Resector Clinical Evaluation Summary

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PX 191
CA No. 99-00000

A 22619

Surgeons / Cases / Sites

<u>Surgeon</u>	<u># of Cases</u>	<u>Institute</u>
Adams, R.	3	Valley View
Bach, B.	1	Rush Surgery Center
Bahr, F.	1	Jax Beach Surgery Center
Baker	3	Houghstien
Barnett, R.	1	Ridgeview Medical Center
Bowen, M.	2	Northwestern Memorial
Brandon, T.	6	Peninsula Regional Med Center
Burke	6	Bayshore Surgery Center
Caborn, D.	1	Jewish Hospital
Cole, B.	2	Oak Park; Rush Surgery Ctr
Cuillo, J.	6	Wm. Beau-Troy; Sinai Surgery Center; Berry Surgery Ctr
Curl, W.	1	North Carolina Baptist
Dugas, R.	6	Lincoln Surgery Center; St. Elizabeth Regional Med Ctr
Field	6	Medical Arts East Surgical Ctr
Gartsman	6	Texas Ortho Hospital
Gillin	1	London Health Sciences Ctr
Hechtman	2	Doctors Hospital
Heekin	1	SLVincent's
Hefferon	1	Same Day Surgery River North
Hunter, R.	3	Aspen Valley
Kulper, S.	6	Baptist Hospital East; HealthSouth Surgical Ctr; Suburban Hospital
Lemos, M.	1	Lahey Clinic
Litchfield	1	London Health Sciences Ctr
Majors, R.	6	HealthSouth Surgery Ctr
Martin, D.	1	North Carolina Baptist
Mazzotta, A.	1	Rush Surgery Ctr
Montgomery, J.	8	Forest Park
Northrop	1	Flagler Hospital
Nuber, G.	3	Northwestern Memorial
Pasgall, S.	1	Forest Park
Poehling	4	North Carolina Baptist
Ranger, P.	1	Sacre-Coeur de Montreal
Rennert, G.	1	Caritas Surgery Center
Selesnick /	1	Doctors Hospital
Canizares		
Siegel, J.	6	Bedford Ambulatory; Northeast Surgical
Smiley, P.	1	Lahey Clinic
Stanish	1	Queen Elizabeth II Hospital
Thompson, M.	2	Lahey Clinic
Uribe / Andary	2	HealthSouth Doctors Hospital
Wilk, R.	1	Lahey Clinic
Zybac	1	Doctors Hospital
41	109	35 Totals

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SN 0050070

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 Dyonics® Series 9000 Electroblade™ Resector Clinical Evaluation Summary Page 6 of 18

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Dynonics® Series 9000 ElectroBlade™ Resector Table of Contents

Automatically go to a specific section by clicking on the desired tab below.

Customer Training CD
Tips for Presentation & Operation
Market Potential
Positioning & Strategy
Pricing Strategy
Targeting
Features and Benefits
Overcoming Objections
The Trident Blade
RF and ElectroBlade

Putting the program into presentation format will allow you to run the customer training session with sound.

Plaintiff's
Trial Exhibit
PX 199
DATE RECEIVED

EXHIBIT
#15
DeLucia
9/19/02
MER

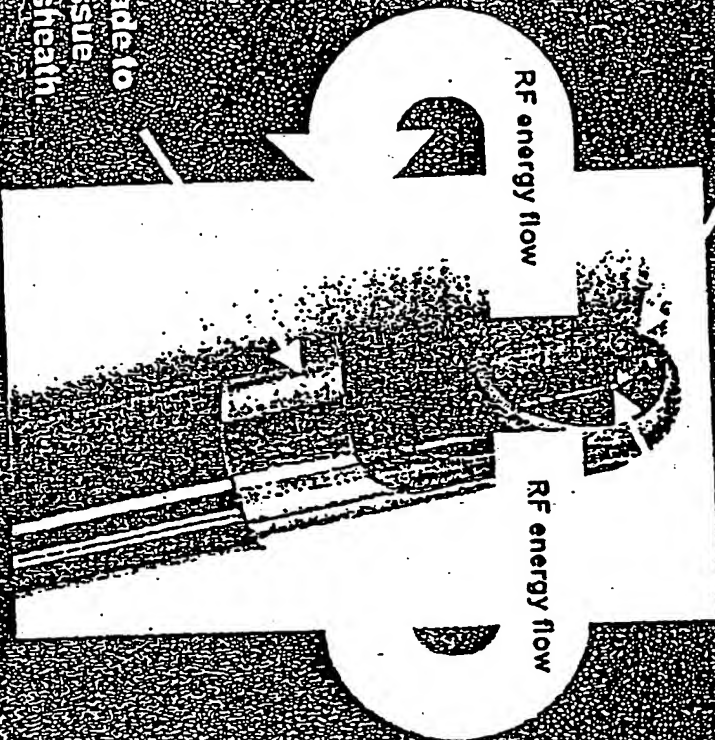
Smith+Nephew

How Does It Work?

ACTIVATED BLADE

Inner blade is activated
with RF energy.

CUTTING EDGE OF BLADE
Energy concentrates at the
cutting surface of the inner blade.



RF energy flow

RF energy flow

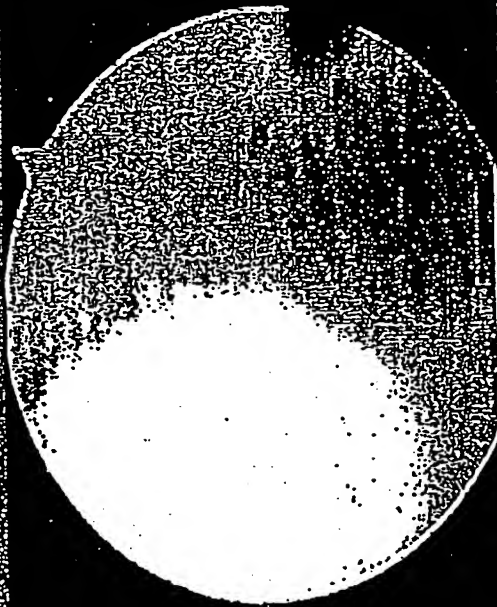
BIPOLAR DESIGN

RF flows from the inner blade to
the return sheath. No tissue
effects occur at the return sheath.

[Back to Table of Contents](#)

Smith & Nephew

Key Feature: Coagulation




Place the blade in the three-quarters closed position using the window lock feature of the Dyonics® Power Shaver System. Placing the blade in this position will allow you to:

- 1) Present the smooth blade surface to the tissue to allow you to use a painting technique when coagulating.
- 2) Use suction to pull bleeding tissue to the blade for coagulation.
- 3) Maintain an opening that will allow for constant suction. Continuous flow will keep the joint temperature low when the RF is on.

We recommend setting the generator to 30 watts and increasing power only as needed. We recommend maintaining constant flow of fluid and stopping the RF component after 10 continuous seconds of use.

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Tips for Optimal Operation and Presentation of the Dyonics ElectroBlade™ Resector

- **The ElectroBlade Resector is NOT designed to use RF energy to ablate tissue** - The ElectroBlade Resector removes tissue through mechanical resection and provides coagulation with RF. Do not present this product as an ablative device.
- **Outer sheath edge** - The outer sheath of the ElectroBlade Resector has an edge. Ensure your surgeons are aware of this edge so they are careful when using the blade near articular cartilage.
- **Use minimum power, time and pressure required to achieve desired result** - Exceeding recommended limits may result in damage to the product.
- **Ensure the entire tip including the return is immersed in saline** - The return is inactive because the energy is spread over a large surface area. If the sheath is not completely immersed in saline, the area where the RF energy returns is reduced. This could allow the return to become an active site when the RF is turned on.

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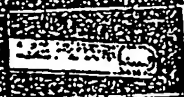
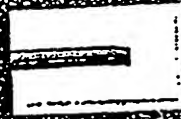
Sales Strategy

Use the Dyonics® Series 9000 ElectroBlade™
Resector to obtain all of the blade business in
high volume competitive accounts

Smith^{US}Nephew

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Pricing Strategy - List Prices



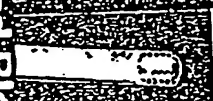
Pen and Blade

\$110



RF Wand or Trident™ Resector

\$150-185



RF Wand and Blade,
ElectroBlade Resector

\$225



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Smith+Nephew

Why Did We Price It This Way?

Price

\$225

- We used pricing of our key competitive products (blade and wand) to set our price.
- The ElectroBlade Resector has completely unique benefits that no other company can offer at this time.
- We are creating an entirely new product platform. This is the first product of its kind and we are creating a floor price for the rest of the products to follow.
- The first RF wand was priced very high compared to the resection products in the market at that time. The increased price was clearly accepted by the industry.
- The ElectroBlade Resector is a high-quality product that costs us much more to make than a standard blade.

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Smith & Nephew

Target Procedures

PRIMARY TARGET PROCEDURE:

Subacromial decompression - The ElectroBlade Resector should perform best in SAD's. The product is well suited for this procedure for the following reasons.

- Traditional snaver blades tend to resect the loose tissue, such as the bursa, much faster than an ablative wand. This is because suction pulls the loose tissue into the blade where it is efficiently cut. Many of your surgeons moved to RF primarily to control the bleeding that a standard shaver blade can't do.
- Many surgeons are concerned about removing the bursal tissue off of the rotator cuff where ablative RF energy could adversely impact viable tissue. The ElectroBlade Resector does not ablate which should help reduce their concerns.
- This procedure can have excessive bleeding that the ElectroBlade Resector can effectively control.
- The simultaneous mechanical resection and coagulation may make it possible for surgeons to reduce their pump pressure reducing effects from extravasation.
- Many surgeons performing this procedure typically use a wand and a blade. The ElectroBlade Resector will allow them to reduce their products (less insertion and removal of devices).

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Smith & Nephew

Target Procedures

SECONDARY TARGET PROCEDURE: We have had success in clinicals in these procedures. However, the evaluations also demonstrated that the products penetration will be lower when compared to SADs.

Tourniquet free knee procedures - Where bleeding is an issue

- ACL, Synovectomy, Lateral Release, Capsular Release

WHAT TO AVOID - This product is not indicated for articular cartilage sculpting or thermal capsular shrinkage. Do not sell the ElectroBlade Resector as an ablative product. You must ensure that your surgeon understands that the product is designed for mechanical resection and the RF component is used for simultaneous coagulation, not ablation.

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Smith & Nephew

Target Products in the O.R.

- **Target disposable resection devices** - Your primary target should be surgeons who use a blade and a wand in a single procedure. In this case, the ElectroBlade Resector may not have a significant cost barrier and can provide the benefit of reduced insertion and removal of devices.
- **Shaver handpiece** - You should focus on surgeons who use the hand control for the shaver. These surgeons should be able to easily control resection and RF coagulation with the foot pedal simultaneously. Surgeons using the foot control for the shaver will have to operate two pedals at the same time to use the simultaneous resection and coagulation feature.
- **Electrosurgical generators** - The ElectroBlade Resector has only been validated with the Valleylab Force FX™, Force FX™-C and Force™ 2 generators. Your account must have these generators to operate the product at this time.
- **Blade preference** - At this time, the ElectroBlade Resector is only available in the 4.5 mm full radius style. You should target surgeons who use this blade style to get your best initial success. A surgeon used to a larger, more aggressive blade may not be satisfied with the cutting performance of the product.

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Smith & Nephew

Target Procedure and Surgeon

Primary: SAD

Secondary: Tourniquet free ACL, lateral release, synovectomy, capsular release, plica resection

Procedures using soft tissue blade and wand

Surgeons Using H.C. on MDU

Valleylab Force FX™,

Force FX™-C and

Force™ 2 generators

4.5 mm

full radius

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Smith & Nephew

Which Accounts Will You Have The Most Success In?

Current Products			Competitive			Smith & Nephew		
Product Combination	MDU Type	Blade Type	Platinum	Gold	Silver	Platinum	Gold	Silver
Blade/Burr/Wand	H.C	F/R						
Burr/Wand	H.C	F/R						
No RF	H.C	F/R						
Blade/Burr/Wand	Pedal	F/R						
Burr/Wand	Pedal	F/R						
No RF	Pedal	F/R						
Blade/Burr/Wand	H.C	Other						
Burr/Wand	H.C	Other						
No RF	H.C	Other						
Blade/Burr/Wand	Pedal	Other						
Burr/Wand	Pedal	Other						
No RF	Pedal	Other						

Primary Target
Secondary Target

Smith & Nephew

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Selling RF Wands and the Dyonics® ElectroBlade™ Resector

In a specific account, some of your surgeons may prefer the ElectroBlade Resector while others will continue to use standard RF. In addition, the ElectroBlade Resector is not indicated for shrinkage or articular cartilage sculpting. In other words, there is a place for both products in the account.

You can use your unique position with the ElectroBlade Resector to bundle an entire resection package and obtain all of the RF business.

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Smith & Nephew

Smith+Nephew

Instructions for Use

Dyonics® Series 7000 RF Arthroscopic Probe

DESCRIPTION

The Dyonics Series 7000 RF Arthroscopic Probe is designed for arthroscopic surgical procedures of the knee, shoulder, ankle, elbow, wrist, and hip. The device consists of a sterile, single-use bipolar probe with suction control, a connector cable and optional hand controls (Figure 1). It is designed for use with a non-sterile, reusable Dyonics Control RF Generator Adaptor. The adaptor and probe are designed for use together as a single unit and plugged into an electrosurgical generator.

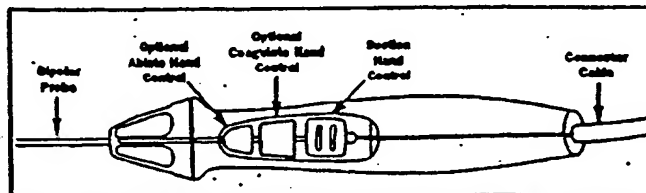


Figure 1. Dyonics Series 7000 RF Arthroscopic Probe with optional hand controls.

INDICATIONS

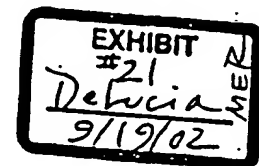
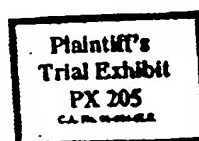
The Dyonics Series 7000 RF Arthroscopic Probe, when used in conjunction with the Dyonics Control RF Generator Adaptor is intended for resection, ablation, or excision of soft tissue; hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, wrist, and hip.

CONTRAINDICATIONS

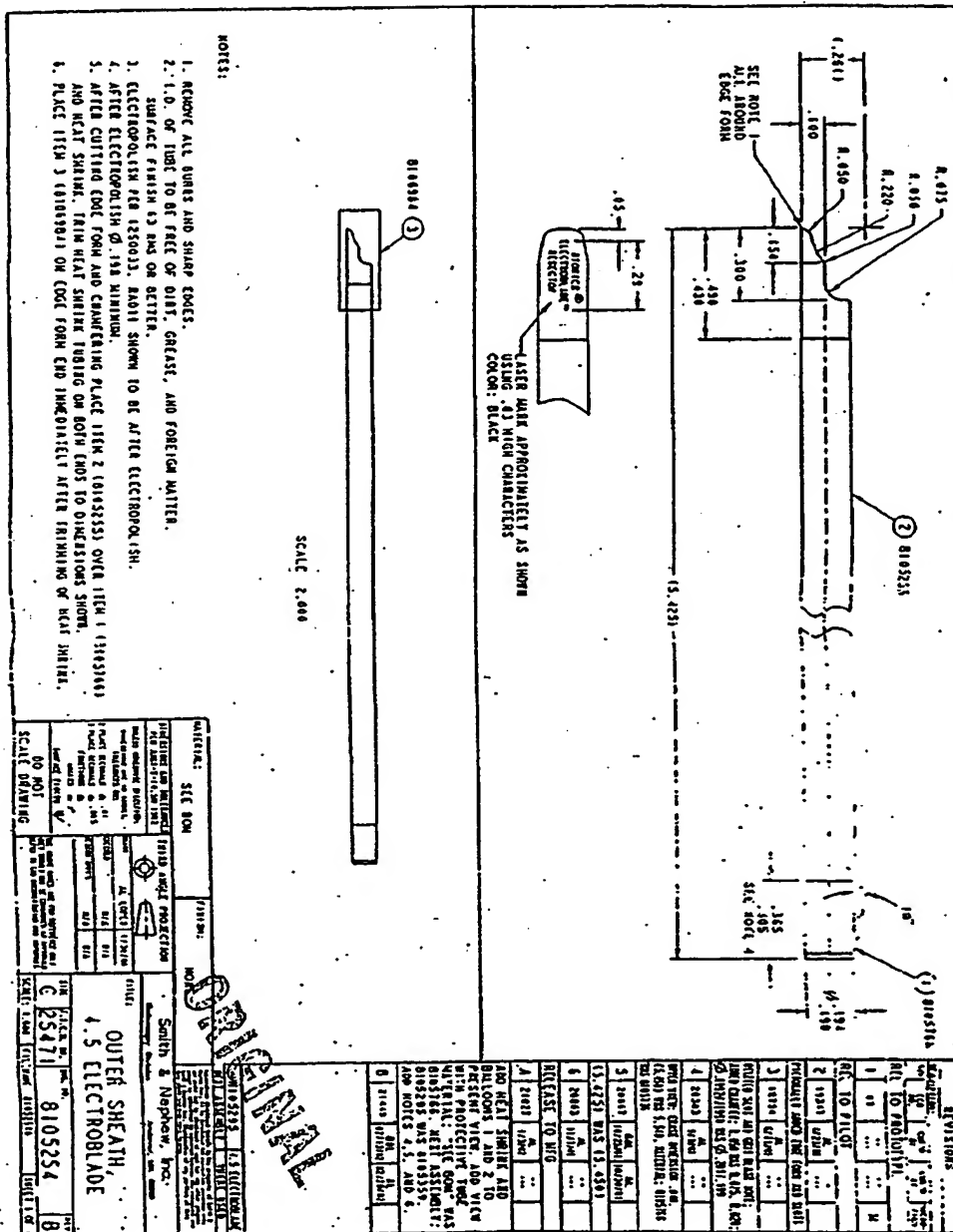
Use of the Dyonics Series 7000 RF Arthroscopic Probe is contraindicated in any non-arthroscopic surgical procedure and in procedures where saline, Ringer's lactate, or other conductive solution is not used as an irrigant. The probe is not appropriate for patients for whom an arthroscopic procedure is contraindicated for any reason. Use of the Dyonics Series 7000 RF Arthroscopic Probe is contraindicated for patients with heart pacemakers or other electronic device implants.

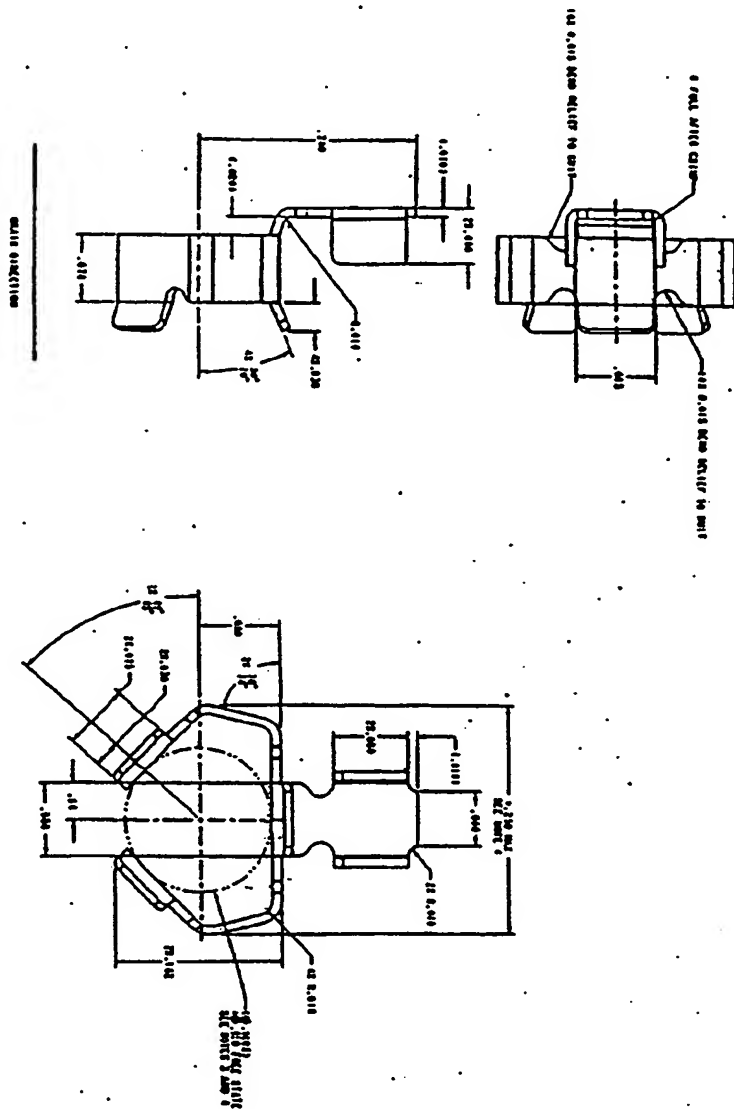
WARNINGS

- Use only with the Valleylab Force FX™ or Force FX™-C Generator and the Smith & Nephew RF Generator Adaptor.
- The power settings provided in this document are for reference purposes. Use the lowest power setting and minimum tissue contact time necessary to achieve the appropriate surgical effect to avoid unintended tissue injury.
- Do not touch the ceramic tip or electrode when power is being applied.
- Avoid touching the ceramic tip or electrode with your fingers or instruments.
- Do not insert or withdraw the probe while power is being applied.
- Inadvertent activation or movement of the electrode outside the field of vision may result in patient injury.
- Avoid unnecessary or prolonged activation between tissue applications as unintended injury may result.
- Avoid bubble accumulation in the joint space during use. The accumulation of bubbles around the working tip of the probe will diminish performance and may produce overheating sufficient to damage adjacent structures.
- Contents sterile. Do not use if package has been opened or damaged.
- Do not reuse any accessories labeled as SINGLE USE.
- Using arthroscopic guidance, ensure that the probe tip is completely surrounded by conductive irrigant solution during use.



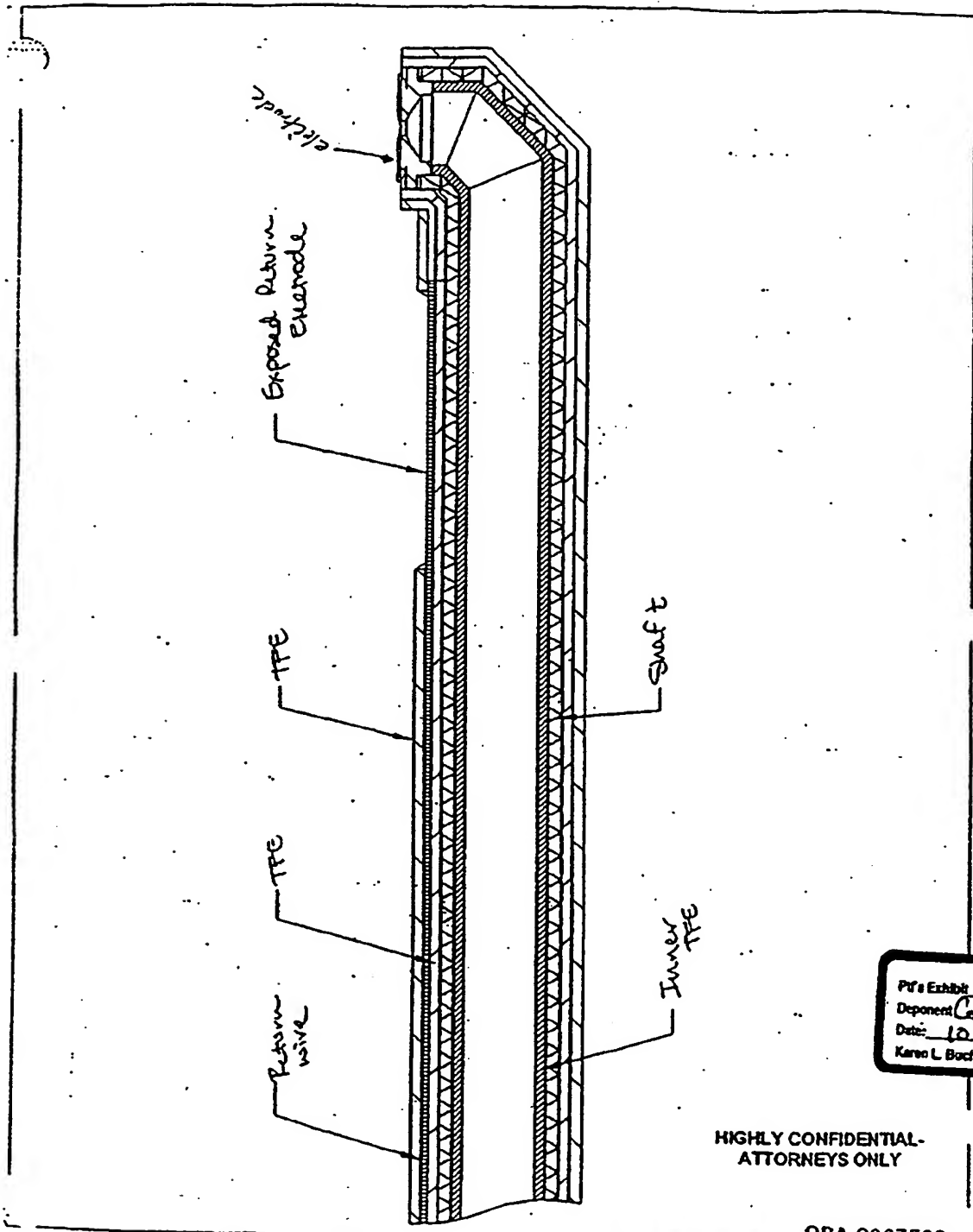
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ORIGINAL

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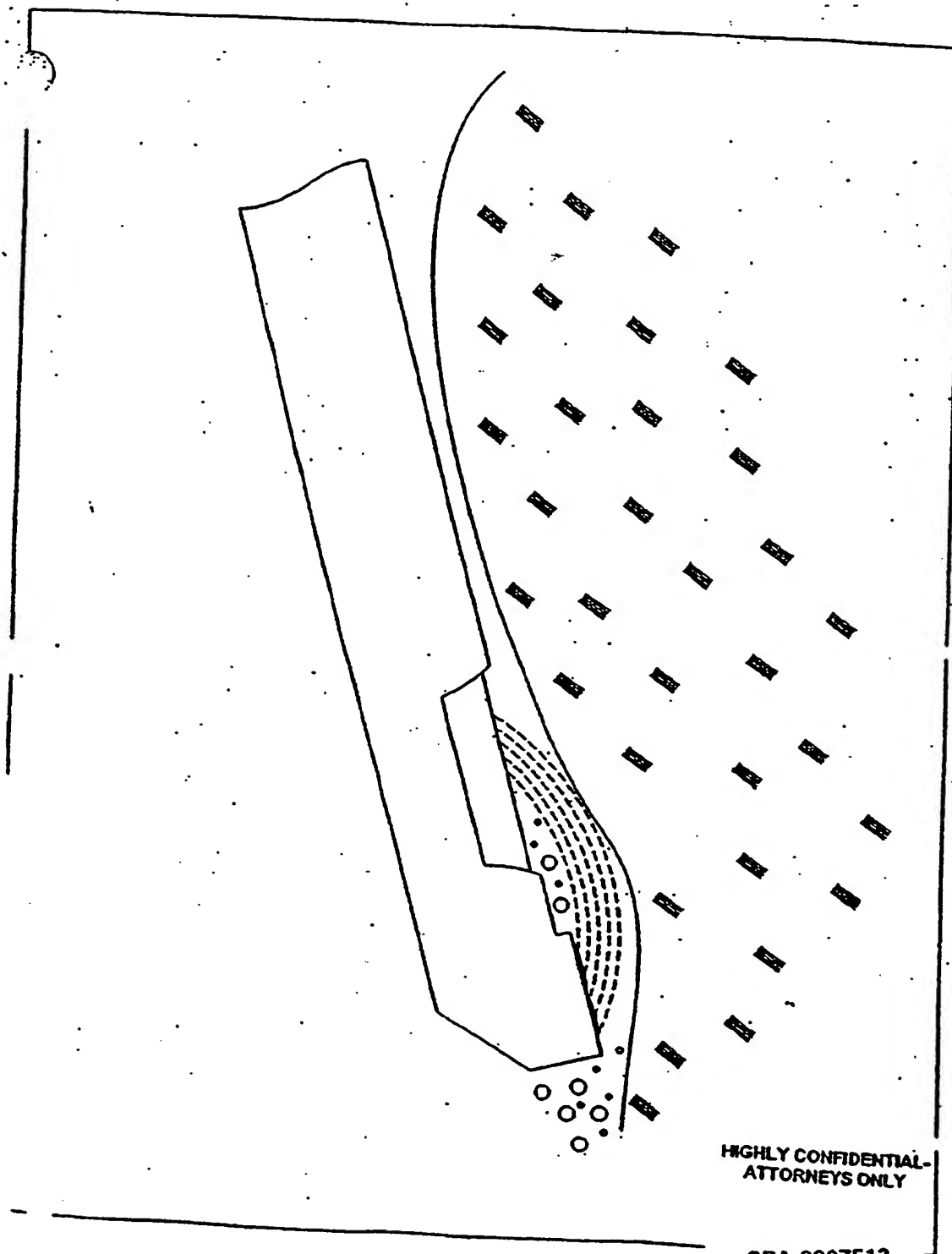
Pt's Exhibit 232
 Deponent Caroline
 Date: 10/11/02
 Karen L. Buchanan

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ORA 0007509

Plaintiff's
 Trial Exhibit
 PX 271
 C.A.N. 8-30452

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ORA 0007512

A 22778

MANUFACTURING PROCESS INSTRUCTION
ORATEC INTERVENTIONS, INC.

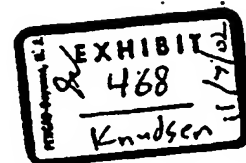
MP100222
Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

Revision History

Rev.	DCO/LAS#	Effective Date	Description of Change	Initiator
01	D010496	08/03/01	New Release	Andy Suresh
02	D010519	08/21/01	<ul style="list-style-type: none">Added MSP200731 to section 5.7, and section 9.1.4 for changing the electrode tip.Revised sections 9.1.3 cleaning the electrode tip, 9.1.6.1 check electrode force with no weld, and 9.2.11 holding the cable up, and 9.3.1 for damaged power wire.	Tan Huynh

R&D W. Knudsen 9/24/01
ME W. Knudsen 9/24/01
QE W. Knudsen 9/24/01



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Plaintiff's
Trial Exhibit
PX 310
C.A. No. 02-00000

ORA 0007458

A 22787

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

1.0 OBJECTIVE

- 1.1 This MPI provides instructions for welding the power wire to the bipolar probe shaft and soldering the return wire for TAC, Chisel Ablation and Ablation Suction shafts.

2.0 REFERENCE

- 2.1 SOP00012 Line Clearance

3.0 AFFECTED DEPARTMENT

- 3.1 Production

4.0 DEFINITIONS

- 4.1 N/A

5.0 EQUIPMENT

- 5.1 Resistance Welder OMC00031
5.2 Power Wire Welding fixture MSP200408
5.3 Safety glasses
5.4 Scale (Ruler), Graduated in 0.01"
5.5 Eraser stripper OMC00104
5.6 Dental mirror
5.7 MSP200731 Electrode Tip Cleaning Tool
5.8 Microscope
5.9 Soldering iron
5.10 Continuity meter

6.0 MATERIALS

- 6.1 Prosat wipes P/N 300073
6.2 IPA

7.0 LINE CLEARANCE AND CLEANING

- 7.1 Clear area of parts not related to this assembly, refer to SOP00012, Line Clearance Procedure.

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A 22788

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

- 7.2 Clean work area by wiping with Prosat wipes.

8.0 SAFETY

- 8.1 If unfamiliar with the use of the resistance welder, contact manufacturing supervisor prior to use.
- 8.2 Wear safety glasses when using resistance welder, if microscope is not used.

9.0 PROCEDURE

9.1 Set-up

- 9.1.1 Set up welding machine.
- 9.1.2 Install Cable Guide MSP200397 on fixture to weld non-suction probes, or Cable guide MSP200668 to weld Suction Probes.
- 9.1.3 Clean the top and bottom electrode prior to lot start and after welding every 30 units. Electrodes should be cleaned using the electrodes cleaning tool MSP200731. Use mirror to inspect any visible signs of damage on the top electrode. Refer to figure #6.
- 9.1.4 Replace the top electrode when the wire or shaft sticks to the electrode, or excessive sparking occurs.
- 9.1.5 Turn on the resistance welder.
- 9.1.6 At the beginning of the lot do the following:
- 9.1.6.1 Check electrode force to 8 lbs with resistance welder on no weld.
- 9.1.6.2 Select the preset schedule (Schedule 1: 1st Pulse = 22.5 %, 2nd Pulse = 45 %).
- 9.1.6.3 Turn the WELD/NO WELD switch to the WELD position.

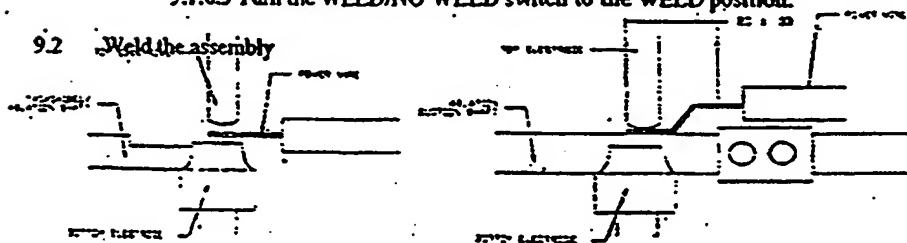


FIG. 1 - POWER WIRE & SHAFT POSITION FOR WELDING

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ORA 0007460

A 22789

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

- ~~9.1.1~~ 9.2.1 IPC: Before welding, verify orientation of the front and rear grommet as shown in Figure 2 and 3.
- 9.2.2 IPC: Inspect the integrity of the tinned wires before welding. They should be tinned all around the wire. There should be no loose wires and the tinned portion should be within $0.10" \pm 0.02"$. If the tinned wire does not meet this criteria, send them to the supporter area to be reworked.
- 9.2.3 Position the shaft to the groove on the shaft supporting block of the welding fixture as shown in Figure 1 with the notch facing up for TAC, Chisel and Ablation shafts, and the tip facing away from the operator for the Ablation Suction and bipolar shafts. For non-suction shafts, make sure that the proximal end of the notch on the shaft is aligned with the edge of the top electrode. Refer to figure 1.
- 9.2.4 Confirm the shaft is resting on the bottom electrode.
- 9.2.5 Align the power wire to the cable guide block of the fixture
- 9.2.6 For the TAC, Chisel and Ablation shafts: The distal tip of the power wire should be located at the proximal end of the notch.
- 9.2.7 For the Ablation Suction shaft: The distal tip of the power wire should be located within 0.2" from the distal end of the crimp ring. Refer to figure 5 for the orientation of the shaft tip for suction shaft.
- 9.2.8 Position the power wire along the groove of the cable guide block of the fixture such that the power wire is resting on top center of the shaft, the power wire is parallel, and the tip of the power wire is flush with the left edge of the top electrode. Refer to figure 1. Take care that the wire is not touching the Crimp Ring on suction probes.
- 9.2.9 Lightly step on the foot pedal so that the top electrode comes down and contacts the power wire.
- 9.2.10 Confirm the left edge of the top electrode tip aligns with the tip of the power wire. Refer to Figure. 1 for power wire and shaft position. Also confirm that the tip of the power wire is centered to the top electrode and on top of the shaft. Refer to figure 6.
- 9.2.11 IPC: During welding, the bottom electrode and the power wire should not touch the crimp ring by holding the cable up from the shaft.
- 9.2.12 If the position of the shaft and power wire meet the above requirements, apply additional pressure to foot pedal to weld the power wire to the shaft.

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ORA 0007461

A 22790

MANUFACTURING PROCESS INSTRUCTION
ORATEC INTERVENTIONS, INC.

MP100222
Rev.02A

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

9.2.13 If In-process Kanban Cards are present at the downstream end of the operation, then use a maximum In-process Kanban Quantity of 5.

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ORA 0007462

A 22791

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

9.3 IPC: Inspect weld spot with a microscope.

9.3.1 Weld spot should show no signs of excessive melting or broken spot on the power wire and shaft.

9.3.2 Wire should not be welded to Crimp Ring (suction)

9.3.3 Wire should not protrude into notch (non-suction).

9.4 Solder the return wire

9.4.1A Cut black integrated cable wire to .100"-.120"

9.4.1 Use a razor blade to scrape clean .125" of the proximal end of the ribbon wire. Solder the black integrated cable wire to the ribbon wire at least .100" distal from the trimmed end of the bottom layer of shrink tubing. The solder joint can not short or contact the shaft.

with the black insulation to up to the end of the ribbon wire.

9.4.2 Clean flux using IPA.

9.4.5 IPC: Gently tug on the power wires to make sure they are securely welded attached in place.

9.6 IPC: Check for shorts between the black and white integrated cable wires using a continuity meter or buzzer.

9.5.7 Assembly of the PVC tubing on suction shaft.

9.7.1 Cut a .500" x .050" piece of polyethylene tubing. Slide the tubing over the proximal end of the shaft.

9.7.2 Heat the distal end of the PVC tubing using a hot box at 350° ± 5° F for 10 seconds.

9.7.2.1 Slide the PVC tubing on to the proximal end of the suction shaft and make sure that there is a range of .08" to .10" gap between the crimp ring and the end of the PVC tubing. Refer to Figure 4 inner TFE to the end of the shaft.

10.0 ACCEPTANCE CRITERIA

10.1 Power wire is securely welded to shaft.

10.2 Weld spot has no signs of excessive melting or broken spots on the power wire.

10.3 The black and white integrated cable wires are not shorted to each other,

* of the shaft so the end is in line with the end of the inner TFE.
9.7.2.2 Heat the polyethylene using a hot box at 350° ± 5° F.

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TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

11.0 DIAGRAM

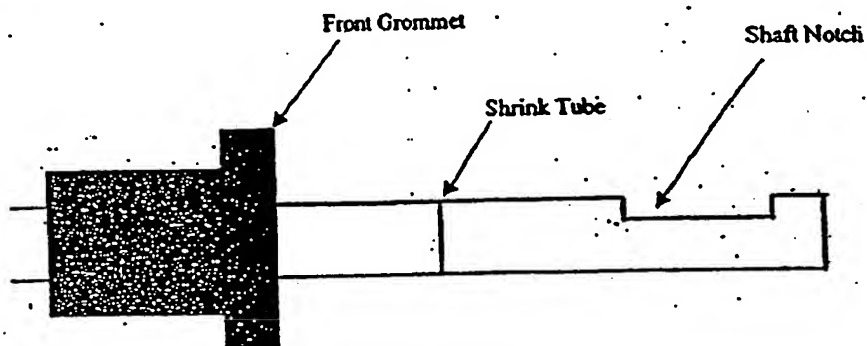


Figure 2: Orientation of Front Grommet on the shaft

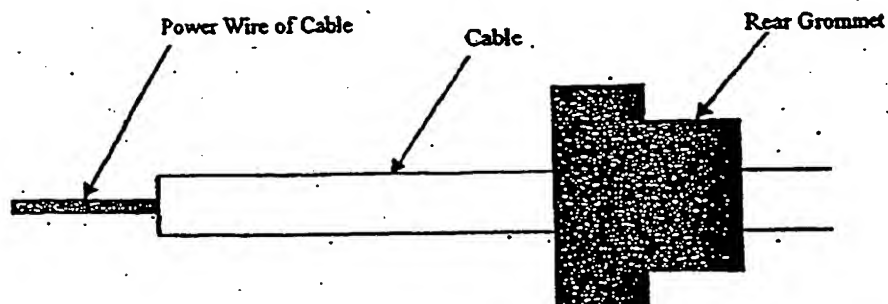


Figure 3: Orientation of Rear Grommet on the Cable

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ORA 0007464

A 22793

TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

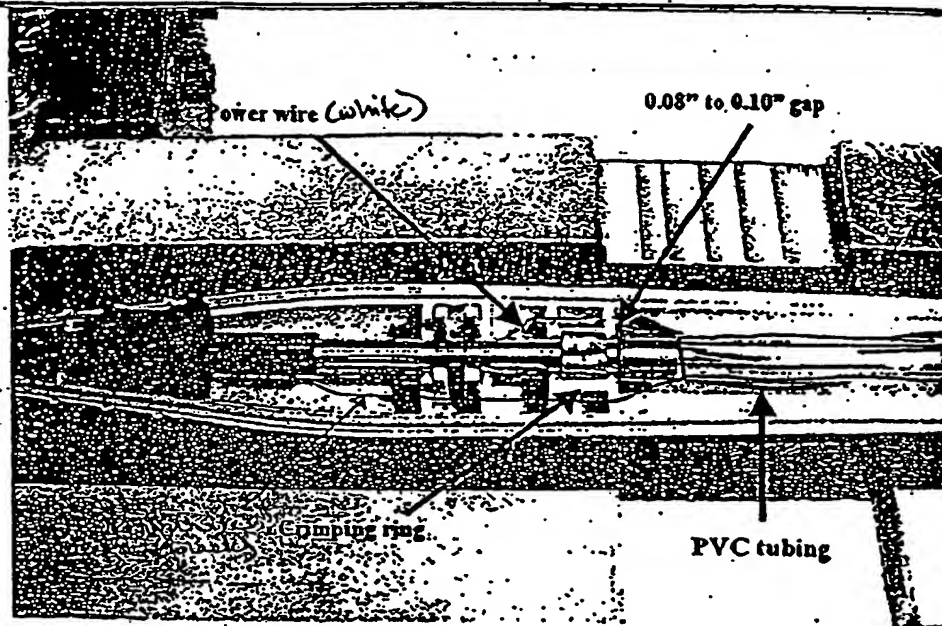


Figure 4: Location of crimp ring on suction and routing of power wire.

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TITLE: CABLE TO SHAFT WELDING FOR INTEGRATED CABLE

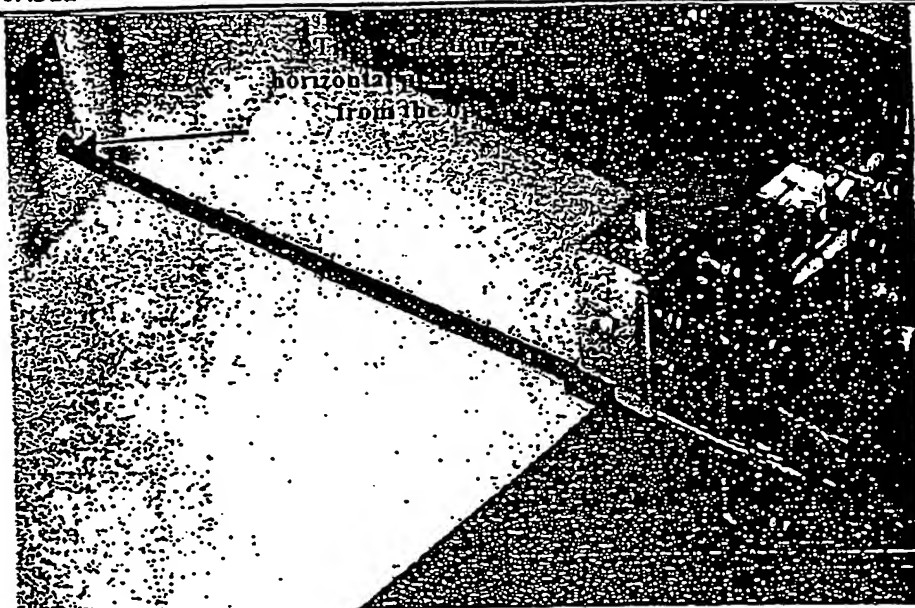


Figure 5: Showing the orientation of the suction tip while resistance welding

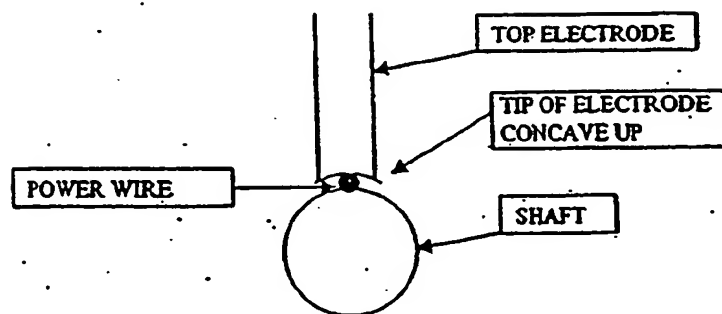


Figure 6: Power wire and Shaft is centered with the Top Electrode

12.0 DOCUMENTATION

12.1 Record manufacturing information, date and sign on the Device History Records (DHR).

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ORA 0007466

A 22795

MANUFACTURING PROCESS INSTRUCTION
ORATEC INTERVENTIONS, INC.

MPI00220A
Rev.01 (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

Revision History

Rev.	DCO/LAS#	Effective Date	Description of Change	Initiator
01	D010496	08/03/01	New Release	Nicole Perez
Temp.	D010524	08/17/01	Revise section 9.1.1	Andy Suresh

R&D Allen Wilson 9/21/01
ME Frank Deane 9/21/01
QE John Long 9/21/01

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ORA 0007467

A 22796

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

1.0 OBJECTIVE

- 1.1 This MPI provides instructions for Preparation of cable wire for TAC, Chisel, Ablation, and Ablation Suction shafts.

2.0 REFERENCE

- 2.1 SOP00012 Line Clearance

3.0 AFFECTED DEPARTMENT

- 3.1 Production

4.0 DEFINITIONS

- 4.1 N/A

5.0 EQUIPMENT

- 5.1 Safety-glasses
5.2 Front Grommet Assembly Fixture (MSP200605)
5.3 Rear Grommet Assembly Fixture
5.4 Wire Strippers, 24 AWG
5.5 Scale (Ruler), Graduated in 0.01"
5.6 Eraser stripper OMC00104
5.7 Solder Pot

6.0 MATERIALS

- 6.1 Prosat wipes P/N 300073
6.2 Lint Free wipes
6.3 70/30 IPA
6.4 Finger cots or Gloves

7.0 LINE CLEARANCE AND CLEANING

- 7.1 Clear area of parts not related to this assembly, refer to SOP00012, Line Clearance Procedure.
7.2 Clean work area by wiping with Prosat wipes.

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A 22797

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

8.0. SAFETY

- 8.1 Wear safety glasses when using Solder Pot.

9.0 PROCEDURE

- 9.1 Prepare Cables in supporter area.

9.1.1 Power wires preparation.

9.1.1.1 For Bipolar Probes strip the grey jacket $2' \pm 0.2'$.

9.1.1.1 For Suction Probes only: Measure the stripped section of the grey jacket. The stripped section should measure $1'' \pm 0.2''$. If not, strip the grey jacket $1'' \pm 0.2''$.

9.1.1.2 Twist or pull one end of cable to remove the outer grey insulation of the wires.

9.1.1.3 Strip power wire to expose the conductor to $0.55''$ to $0.65''$ and then twist the small wires together. If needed use finger cots or gloves to twist the wires.

9.1.1.4 Dip the twisted wires into the 70/30 IPA and dry with lint free wipes.

9.1.1.5 Dip the end of the stripped section into a solder pot to tin $0.20''$ to $0.30''$ of the wire tip. *NO 9/21/01*

9.1.1.6 Trim the exposed conductor such that the tinned section is $0.10'' \pm 0.02''$.

9.1.1.7 IPC: Inspect if $0.10'' \pm 0.02$ of the tip of the power wires are fully tinned. *are NO 9/21/01*

9.1.1.8 For cables with TC Wires, strip approximately $0.3'' \pm 0.1$ from each end of the TC Wires.

- 9.2 For shafts that are coated by supplier, inspect the coated shaft for the following:

9.2.1 Visually inspect the insulation under 1X magnification with probe held at $18''$ away.

9.2.1.1 Reject any pinholes, cuts or deep scratches exposing metal.

9.2.1.2 Reject if scratches, embedded particles, discoloration spots are located within distal $1''$ of probe.

9.2.1.3 For scratches, embedded particles, discoloration spots located beyond distal $1''$ of probe, reject if:

9.2.1.3.1 More than four are found in any combination.

9.2.1.3.2 Any scratch longer than $0.08''$.

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ORA 0007469

A 22798

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

9.2.1.3.3 Any embedded particles or discoloration spot larger than 0.05" in diameter.

9.2.2 Put the protective sleeve over the coated shaft.

9.3 Assemble cable and PVC tubing on the rear grommet from supporter area.

9.3.1 For non-suction probes, slide the rear grommet over the cable to about 3.5" from the tip of the power wire using rear grommet fixture. Refer to Figure 2 for orientation of the rear grommet on the cable.

9.3.2 Assemble the front grommet on to the shaft using the front grommet assembly fixture. Refer to Figure 1 for orientation of the front grommet on the shaft.

9.3.3 For suction probes ^{and bigger probes} slide the rear grommet over the cable and the PVC tubing to about 3.5" from the tip of the power wire. Make sure that the PVC tube is inserted into the larger hole in the rear grommet. Refer to Figure 2 for orientation of the rear grommet on the cable.

9.3.4 ^{For all probes & retain position} Assemble the front grommet onto the shaft using the front grommet assembly fixture MSP200605 refer to figure 1 for orientation of front grommet on the shaft.

9.3.5 Note: To rework shafts with excess power wire, use a file to take off the excess wire, by filing down the excess wire until the shaft is free of excess wire.

10.0 ACCEPTANCE CRITERIA

10.1 Visually inspect the stripped power wire if tinning is within spec of 0.10 ± 0.02 .

10.2 Visually inspect if the tinned section of the power is not frayed.

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TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

11.0 DIAGRAM

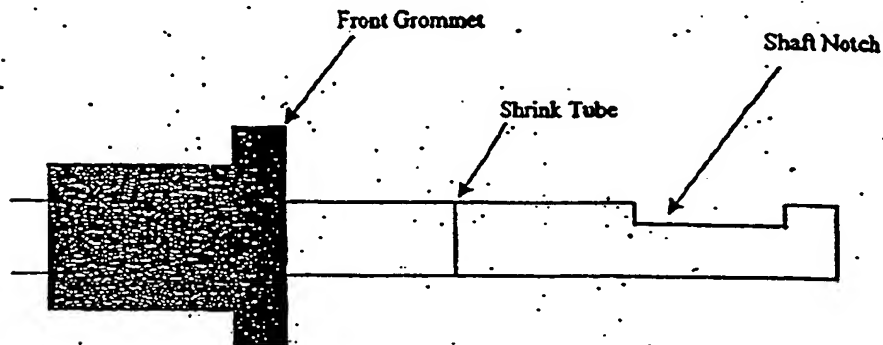


Figure 1: Orientation of Front Grommet on the shaft

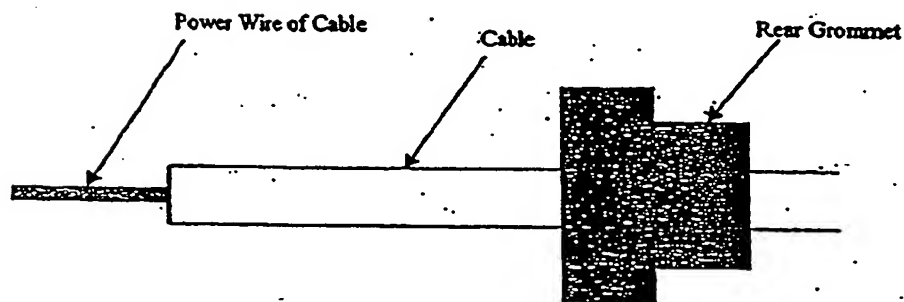


Figure 2: Orientation of Rear Grommet on the Cable

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Page 5 of 6

ORA 0007471

A 22800

MANUFACTURING PROCESS INSTRUCTION
ORATEC INTERVENTIONS, INC.

MP100220
Rev.01 (Temp.)

TITLE: CABLE AND SHAFT PREPARATION FOR INTEGRATED CABLE PROBE

12.0 DOCUMENTATION

12.1 Record manufacturing information, date and sign on the Device History Records (DHR).

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Page 6 of 6

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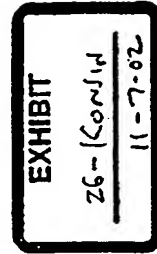
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A 22802

Competitive Selling ArthroCare

Rob Griffin



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A 22803

Managing Surgeon Expectations

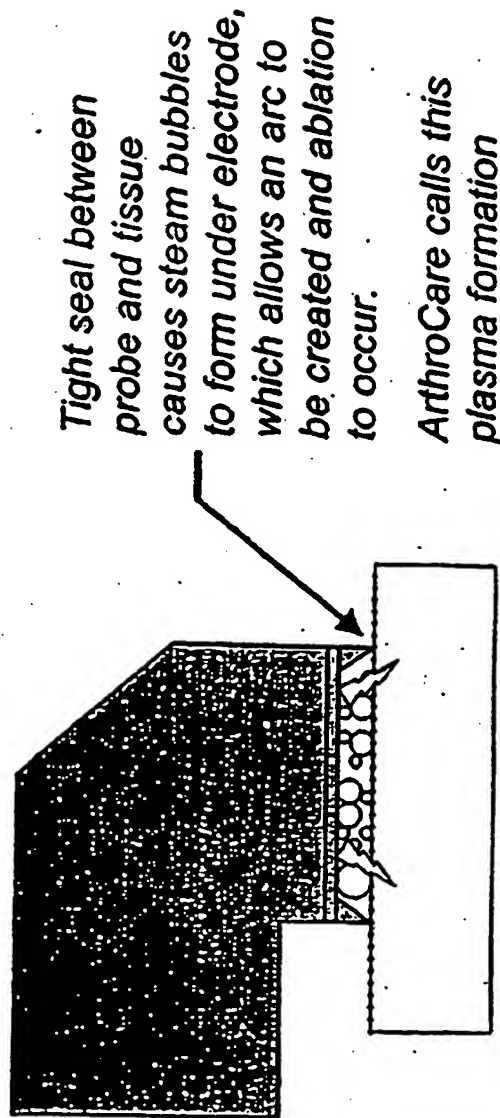
- Saphyre - Suction Probes
 - Saphyre suction design will clear bubbles and debris quickly, and efficiently
 - During use, keep the electrode level with the target tissue for optimal evacuation of bubbles
 - Start your surgeon at the pre-set of 120 watts
 - Suggest setting the suction control valve to wide-open

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Managing Surgeon Expectations

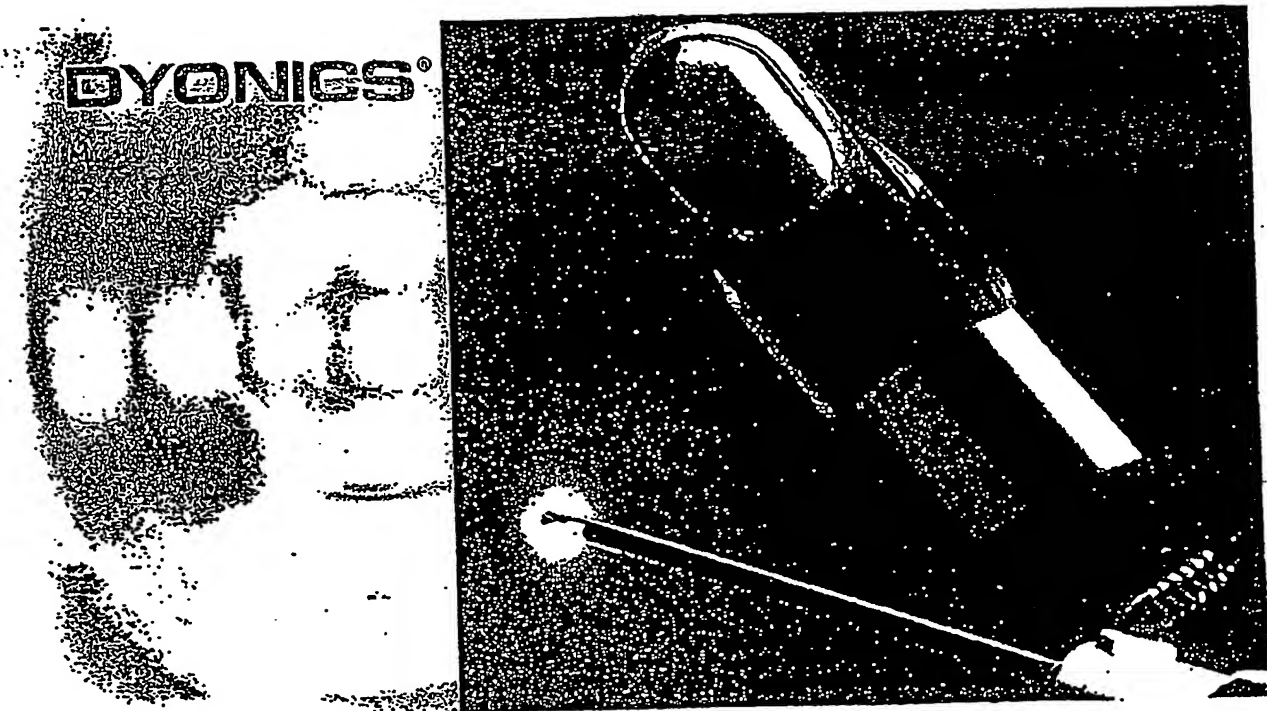


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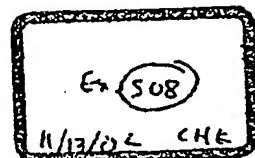
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**Dyonics® Series 9000
ElectroBlade™ Resector**



***The world's first arthroscopic
product to mechanically resect
soft tissue and simultaneously
provide coagulation!***

Smith+Nephew



SN 004922.1

**Plaintiff's
Trial Exhibit
PX 335**

A 22851

Dyonics® Series 9000 ElectroBlade™ Resector

Coagulation

place the blade in the three-quarter closed position using the window lock feature of the Dynabuck Power Saver System. Picting the blade in this position will allow you to:

1. Freeze the smooth blade surface to the desired thickness you want a polishing technique when comping.
2. Use the machine to put bleeding down to the blade for comping.

Resection with Simultaneous

Coagulation

This function is best performed in the following manner:

1. Activate RF energy via bipolar probe.
2. Address shares for resection.
3. Turn off shares.
4. Turn off RF.

The R.F. should be the last item turned off to effectively conserve the manufactured device during reception.

Set-Up Instructions

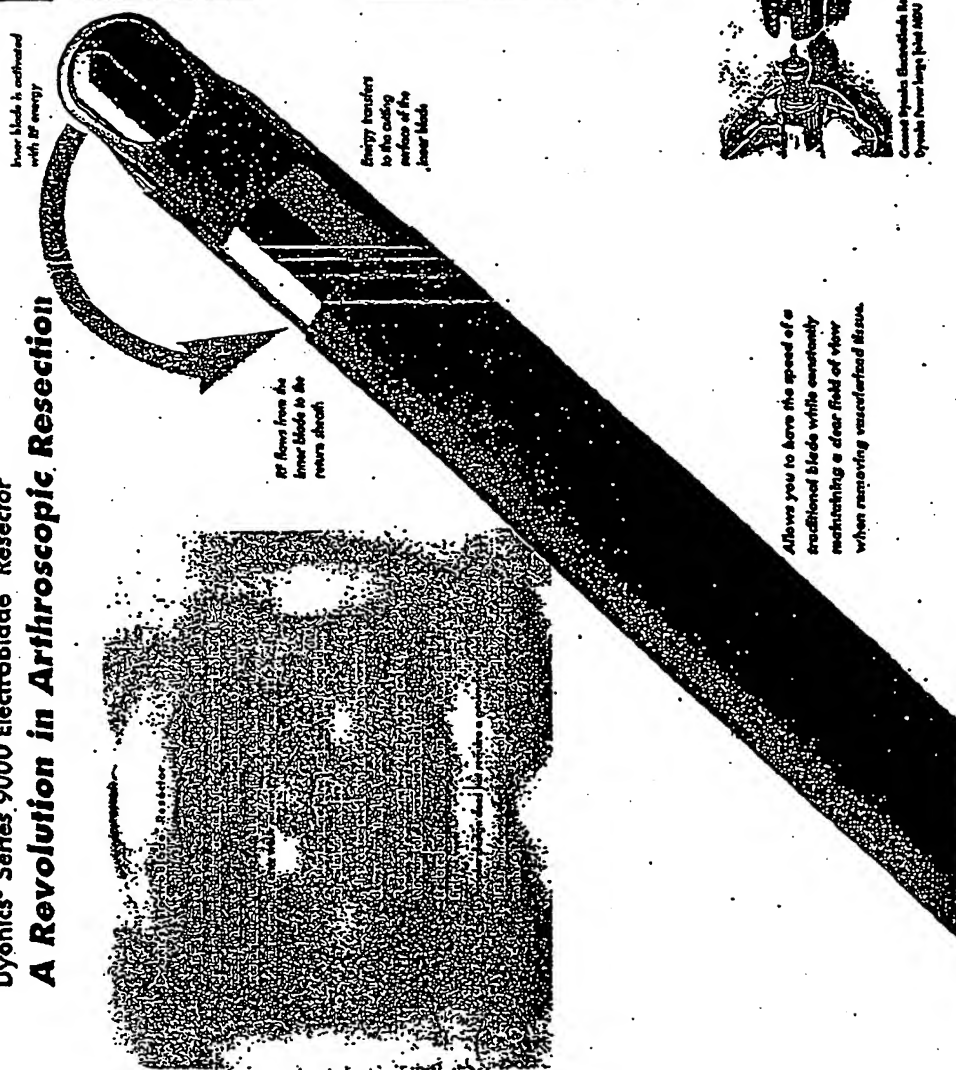


**Why Dynex Characterizes Whetzer and Lee
As the result of your personal encounter**



**Control Systems Electronics Research in the
Dynamics Power Supply Joint AGU**

Allows you to have the speed of a traditional blade while constantly maintaining a clear field of view when removing vascularized tissue.



Inner blade is activated with RF energy

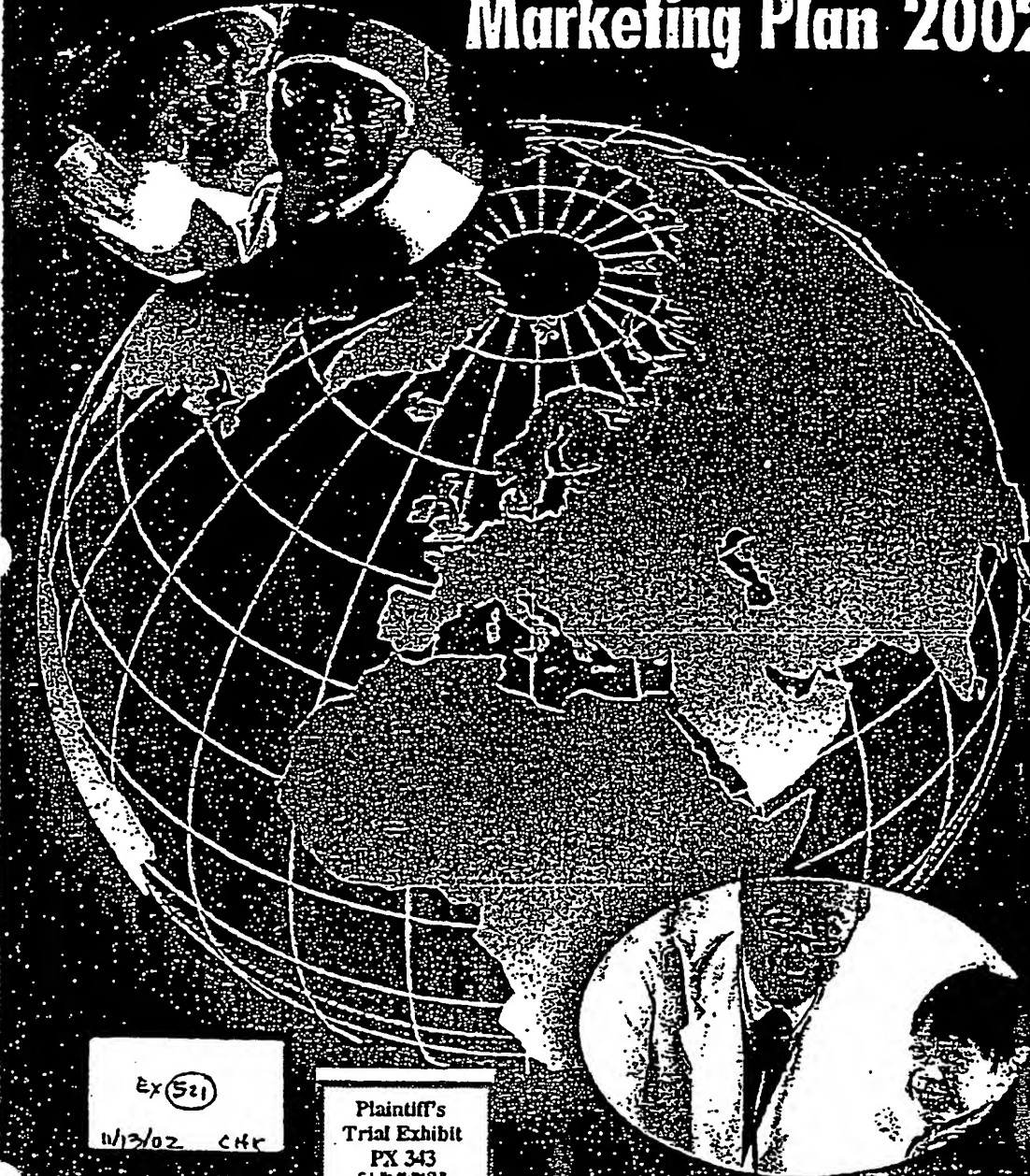
Energy transfers
to the coating
surface of the
inner blade

off flows from the inner blade to the return shaft.

Smith & Nephew, Inc.

Endoscopy Division

Marketing Plan 2002



Ex (521)

11/3/02 CHR

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Smith & Nephew

SN 0054884

A 22856

Competitor	Strengths	Weaknesses	Opportunities	Threats
Oratec	Most extensive experience with thermal shrinkage Continually improve existing product (i.e., Vulcan system, new suction probes) Only device with temperature control	Perceptions/reality of monopolar safety issue Slowly gaining acceptance in crowded ablation market Niche supplier Vulcan regarded as too aggressive for ablation - "firestick"	Establish temperature-control platform for large potential segments such as articular cartilage Differentiate as clinical leader w/published studies Partner with arthroscopy supplier for expanded representation	Poor long-term clinical results w/shrinkage Competitors produce equal or better shrinkage results Competitors leverage/bundle with other equipment Company's spine segment will siphon off funds for arthroscopy
Mitek	Solid ablation product; recent introduction of thermal version Leverage with shoulder products Respected, physician-focused salesforce Recent upgrades include temperature controlled generator Strongest European presence due to Ethicon	OEM from Gyrus Current focus on shoulder segment only Has not established credibility for thermal shrinkage. Design does not allow for suction; use "sheath" with limited success	Innovative will expand full line opportunity Establish clinical efficacy/superiority of VAPR II for thermal shrinkage and ablation Develop next-generation devices	Share same niche position as Arthrex/ArthroCare, confusing to customers OEM product < margins, profitability will decline w/aggressive bundling
Arthrocare	First to market w/bipolar ablation product Considered "gold standard" for product performance Leverage with Arthrex product in US Strong patent position	Lack Mitek's financial resources Niche player in overall arthroscopy market	Leverage wands with Arthrex products Establish clinical efficacy/superiority of thermal products	Declining profit margins with OEM/free box; declining ASP for leverage Increased competitors will speed market maturation Inability to gain broad acceptance for articular cartilage will snuff growth
Stryker	Strong recognition in visualization market	#3 position in powered resection market	Lever RF for a complete system sale	Poor customer acceptance if function appears inferior to Arthrocare or Mitek
Linvatec	Broad product line Perceived as low-cost supplier	Monopolar device minimally differentiated from "Bovie pencil" Low customer recognition/acceptance of device	Establish clinical equivalence to established competitors and low-cost platform Broad bundling capability	Failure to create a distinction from Bovie Nonexistent promotional efforts

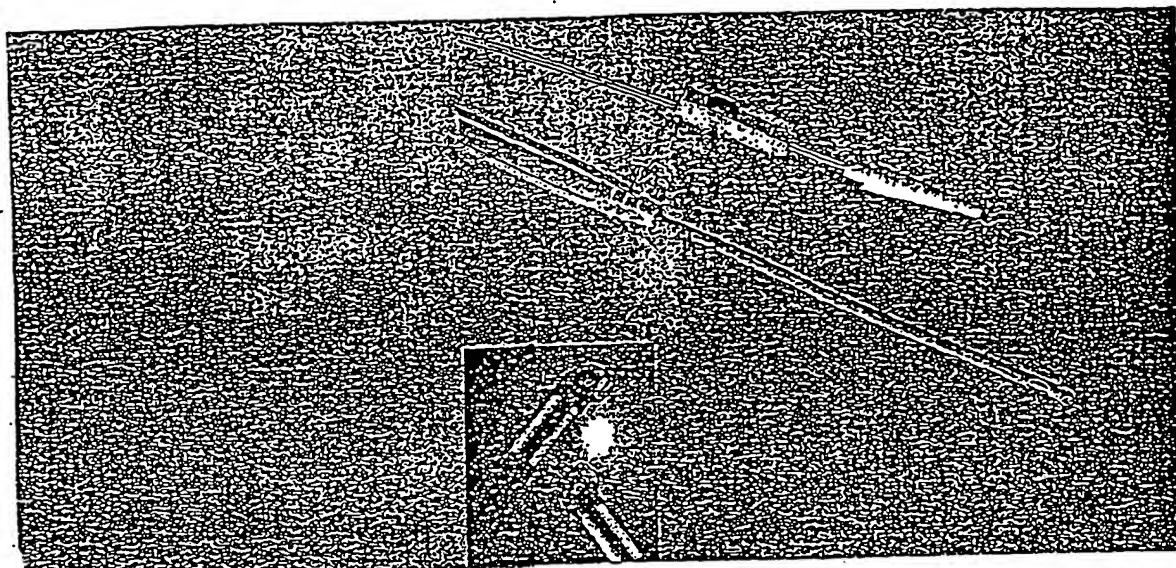
Figure 7-60 RF Competitor SWOT Analysis

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<p>Yulcan™ Saphyre™ Bipolar Ablation Probes</p> <p>RESEDA ① Δ</p> <p>These bipolar probes are used to ablate tissue in the treatment of cardiac arrhythmias. They are made of stainless steel and have a length of 10 cm. The probes are used in conjunction with a radiofrequency generator.</p> <p>Product Description</p> <p>The probes are made of stainless steel and have a length of 10 cm. They are used in conjunction with a radiofrequency generator to ablate tissue in the treatment of cardiac arrhythmias.</p> <p>Indications for Use</p> <p>The probes are used to ablate tissue in the treatment of cardiac arrhythmias. They are used in conjunction with a radiofrequency generator.</p> <p>Contraindications</p> <p>The probes are contraindicated in patients with a known hypersensitivity to the materials used in the probes.</p> <p>Instructions for Use</p> <p>1. The probe is inserted into the patient's heart through a catheter.</p> <p>2. The probe is positioned at the site of the arrhythmia.</p> <p>3. The radiofrequency generator is activated, and the probe is used to ablate the tissue.</p> <p>4. The probe is removed from the patient's heart.</p> <p>5. The patient is monitored for any complications.</p>	<p>Yulcan™ Saphyre™ Bipolaire ablationprobes</p> <p>RESEDA ① Δ</p> <p>Ces sondes bipolaires sont utilisées pour ablater du tissu cardiaque dans le traitement des arythmies cardiaques. Elles sont fabriquées en acier inoxydable et ont une longueur de 10 cm. Elles sont utilisées en conjonction avec un générateur à radiofréquence.</p> <p>Description du produit</p> <p>Les sondes bipolaires sont fabriquées en acier inoxydable et ont une longueur de 10 cm. Elles sont utilisées en conjonction avec un générateur à radiofréquence pour ablater du tissu cardiaque dans le traitement des arythmies cardiaques.</p> <p>Indications d'usage</p> <p>Les sondes bipolaires sont utilisées pour ablater du tissu cardiaque dans le traitement des arythmies cardiaques. Elles sont utilisées en conjonction avec un générateur à radiofréquence.</p> <p>Contre-indications</p> <p>Les sondes bipolaires sont contre-indiquées chez les patients présentant une hypersensibilité connue aux matériaux utilisés dans les sondes.</p> <p>Instructions d'usage</p> <p>1. La sonde est introduite dans le cœur du patient à travers un cathéter.</p> <p>2. La sonde est positionnée au site de l'arythmie.</p> <p>3. Le générateur à radiofréquence est activé, et la sonde est utilisée pour ablater le tissu.</p> <p>4. La sonde est retirée du cœur du patient.</p> <p>5. Le patient est surveillé pour toute complication.</p>	<p>Yulcan™ Saphyre™ Sondas de ablación bipolares</p> <p>RESEDA ① Δ</p> <p>Estas sondas bipolares se utilizan para ablar tejido cardíaco en el tratamiento de las arritmias cardíacas. Están fabricadas en acero inoxidable y tienen una longitud de 10 cm. Se utilizan en conjunción con un generador de radiofrecuencia.</p> <p>Descripción del producto</p> <p>Las sondas bipolares están fabricadas en acero inoxidable y tienen una longitud de 10 cm. Se utilizan en conjunción con un generador de radiofrecuencia para ablar tejido cardíaco en el tratamiento de las arritmias cardíacas.</p> <p>Indicaciones de uso</p> <p>Las sondas bipolares se utilizan para ablar tejido cardíaco en el tratamiento de las arritmias cardíacas. Se utilizan en conjunción con un generador de radiofrecuencia.</p> <p>Contraindicaciones</p> <p>Las sondas bipolares están contraindicadas en pacientes con una hipersensibilidad conocida a los materiales utilizados en las sondas.</p> <p>Instrucciones de uso</p> <p>1. La sonda se introduce en el corazón del paciente a través de un catéter.</p> <p>2. La sonda se posiciona en el sitio de la arritmia.</p> <p>3. El generador de radiofrecuencia se activa, y la sonda se utiliza para ablar el tejido.</p> <p>4. La sonda se retira del corazón del paciente.</p> <p>5. El paciente es monitoreado por complicaciones.</p>	<p>Yulcan™ Saphyre™ Bipolare Ablationssonden</p> <p>RESEDA ① Δ</p> <p>Diese bipolare Sonden werden zur Ablation von Herzmuskelgewebe bei der Behandlung von Herzrhythmusstörungen eingesetzt. Sie bestehen aus Edelstahl und haben eine Länge von 10 cm. Sie werden zusammen mit einem Radiofrequenz-Generator verwendet.</p> <p>Produktbeschreibung</p> <p>Die bipolaren Sondenspitzen sind aus Edelstahl gefertigt und haben eine Länge von 10 cm. Sie werden mit einem Radiofrequenz-Generator zur Ablation von Herzmuskelgewebe eingesetzt.</p> <p>Anzeigen für den Einsatz</p> <p>Die bipolaren Sondenspitzen werden zur Ablation von Herzmuskelgewebe bei der Behandlung von Herzrhythmusstörungen eingesetzt. Sie werden zusammen mit einem Radiofrequenz-Generator verwendet.</p> <p>Gegenanzeigen</p> <p>Die bipolaren Sondenspitzen sind kontraindiziert bei Patienten mit einer bekannten Überempfindlichkeit gegen die Materialien der Sonde.</p> <p>Benutzungsanleitung</p> <p>1. Die Sonde wird über einen Katheter in das Herz des Patienten eingeführt.</p> <p>2. Die Sonde wird an der Stelle der Arrhythmie positioniert.</p> <p>3. Der Radiofrequenz-Generator wird eingeschaltet, und die Sonde wird zur Ablation des Gewebes genutzt.</p> <p>4. Die Sonde wird aus dem Herzen des Patienten entfernt.</p> <p>5. Der Patient wird auf Komplikationen überwacht.</p>
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Saphyre™ Bipolar Ablation Probes

Smith & Nephew ElectroThermal™ Arthroscopy System (EAS™)



Sales Guide

Prepared by the Marketing and
Sales Training Departments

Software Upgrade Guide
on Page 13

Plaintiff's
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PX 390
CA No. 03-03-02

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A 23162

Introduction

The acquisition of ORATEC Interventions by Smith & Nephew Endoscopy Division provides a unique opportunity to combine the strengths of Smith & Nephew in arthroscopic visualization and resection with the technology leadership position ORATEC had established in radiofrequency (RF) systems and applications. The ORATEC product line has been known as the "monopolar" RF technology in the marketplace, and there certainly are numerous advantages to the use of monopolar RF energy delivery in certain applications. As we further the integration of the former ORATEC products into the Smith & Nephew Electrothermal Arthroscopy System (EAS), we want to act quickly to extend the product offering to include bipolar ablation.

This Sales Guide will initiate the launch of the new Saphyre™ Bipolar Ablation Probe product line. The addition of Saphyre Bipolar Ablation Probes rounds out our electrothermal arthroscopy product line. The Smith & Nephew EAS is the only arthroscopy system available anywhere that can operate in both monopolar and bipolar energy delivery modes. Our customers will now have the convenience and freedom of choice to move between these two tools freely, using the Vulcan® Generator. You can look forward to some true competitive advantages from these customer benefits.

In the Sales Guide, you'll learn about Saphyre Bipolar Ablation Probe Features and Benefits, how these products compare with competitors, and our strategies for approaching customers successfully. A key element to keep in mind is that we will not obsolete the monopolar Ablation Probe product line. Smith & Nephew has many customers that are completely satisfied with the performance of the monopolar ablation products. It is undesirable for us and undesired by the customers to convert these accounts to bipolar ablation. You will be given some very specific direction regarding account targeting and the rollout of Saphyre Bipolar Ablation products. Let's use the launch of Saphyre Bipolar Ablation Probes to grow the business!

Please study the contents of the Sales Guide thoroughly. This material complements the Web training material. We expect you to know this material and to return and pass the enclosed Assessment before your sales samples and literature will be sent to you. Questions concerning any of this information or any issue relating to the launch of Saphyre Bipolar Ablation Probes should be addressed to the Marketing Department.

Thank you and Good Selling!!

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Product Description

Saphyre bipolar ablation probes bring bipolar modality to life for the Smith & Nephew Vulcan generator. Simply put, the probes are disposable, bipolar electrosurgical probes for cutting, ablating and coagulating soft tissue. But there is also so much more!

Saphyre bipolar ablation probes are designed to be competitive with existing bipolar and monopolar products currently on the market. They are intended to build RF sales where monopolar Smith & Nephew products have been unable to gain ground against competitive bipolar ablation sales.

To this end, Saphyre probes offer several features to stand out against the competition.

- Jewel cut, notched electrode for fantastic ablation performance
- Protected back-side of the distal shaft to minimize collateral tissue damage, called the CoolBack™ insulated shaft
- Integrated Cable
- Excellent coagulation ability
- Suction and non-suction available
- High profile tips available
- Part of the Vulcan family, with auto-probe recognition and software controls

Saphyre probes stand out with a gray color-scheme to differentiate it from other Smith & Nephew probe lines. The double-walled shaft insulation and integrated cable connector are both gray, as is the box label color scheme.

The Saphyre line is available in the following models:

Saphyre 90°, 3mm
Saphyre 60°, 3mm
Saphyre 90°, 3mm High Profile

Saphyre 90°, 3mm with Suction
Saphyre 60°, 3mm with Suction
Saphyre 90°, 3mm High Profile with Suction

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Saphyre™ Product Objectives

Market Objectives

Saphyre probes put the Smith & Nephew Vulcan ElectroThermal Arthroscopy System ahead of all competitors. Our objectives are to:

- ♦ Successfully launch Saphyre probes with target sales of \$3.4 million in 2002
- ♦ Demonstrate Smith & Nephew's ElectroThermal Arthroscopy System superiority using Saphyre probes
- ♦ Capture an additional 8% market share in ablation, to a total 18% share
- ♦ Abstain from cannibalization of current monopolar ablation business

Customer Targets

Prioritizing your customers into specific targets will give you the best chance of capturing significant bipolar ablation business while minimizing the impact on your current monopolar ablation shipments. Here are the customer targets we want you to go after.

1. **Platinum Smith & Nephew Endoscopy Dyonics™ Shaver accounts with competitive RF products.**

You can offer these customers the terrific advantage of having a single supplier for all their arthroscopic resection instruments. Streamlined ordering and pricing packages are available for them.

2. **Accounts that *exclusively* use competitive (bipolar) ablation, but have the Vulcan generator in place for temperature control procedures.**

These customers should give you an instant "in" because they already use Vulcan generator for temperature control with TAC probes. Your objective is to get them to evaluate and convert to Saphyre bipolar ablation probes. Offer them the advantage of consolidating to one RF arthroscopy system.

NOTE:

We are specifically *not targeting* accounts where Smith & Nephew monopolar ablation probes are used exclusively or extensively. We already have the business there! Let's use the launch of the Saphyre probes to obtain new business. Do not cannibalize our existing monopolar probe volume. These customers are happy with their monopolar ablation products, and should not be visited with Saphyre probes unless independently requested by the surgeon.

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Product Summary

♦ *Smith & Nephew ElectroThermal Arthroscopy System*

- ❖ *The most complete system for Electrothermal Arthroscopic surgery available today!*
- ❖ *The only system that combines rapid-response tissue temperature control with automatic probe recognition.*
- ❖ *The world leader in thermal modification of soft tissues in arthroscopic procedures.*
- ❖ *The only system offering probes with integrated disposable cables. No need to clean and resterilize reusable cables!*

♦ *Saphyre Probe*

- ❖ *The only probe available with CoolBack™, virtually eliminating risk of tissue damage from a hot return electrode that may be out of the field of view.*
- ❖ *In combination with the probe-recognition of the Vulcan generator and integrated cable, the most convenient choice in bipolar ablation.*
- ❖ *Part of the Smith & Nephew EAS family of probes, the most complete Electrothermal Arthroscopy System on the market.*
- ❖ *The newest, easiest to use bipolar ablation probe on the market today!*

♦ *Monopolar Ablation*

There is no plan to obsolete or reduce emphasis on this portion of the product line. In accounts satisfied with monopolar ablation, there is no need to launch bipolar. Here is a synopsis of the positioning of monopolar ablation:

- ❖ *Exceptional ablation performance within the Smith & Nephew EAS family.*
- ❖ *The convenience of integrated cable with the confidence of monopolar technology.*
- ❖ *Lower cost for the customer than bipolar ablation probes from competitors or from Smith & Nephew (see price list for details).*
- ❖ *Monopolar is established and accepted technology for both temperature control and ablation applications.*

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Smith & Nephew's Strengths and Weaknesses

To expand Smith & Nephew's strong leadership position in the arthroscopy market an all-in-one RF system has been added to Smith & Nephew's broad repertoire of products for resection, repair, visualization, and access. The new all-in-one ElectroThermal Arthroscopy System has key strengths to solidify Smith & Nephew's position as market leader of the arthroscopic resection market while overcoming the obstacle of being known as the "monopolar system":

Strengths	Weaknesses
<ul style="list-style-type: none">• Broadens comprehensive line of quality products for arthroscopic resection, repair, visualization, and access by creating a single source supplier• Large global sales force with a broad procedure knowledge and strong customer relationships• Already established market share in the arthroscopy market with \$27 million in sales for 2001• All-in-one system allows the customer to resect, contract, and coagulate with monopolar and bipolar capabilities-no one else in the market can provide this• Strengthens leadership position in the arthroscopic market and specifically arthroscopic resection	<ul style="list-style-type: none">• Vulcan system has been known as the "monopolar system"

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Smith & Nephew Market Strategies

The Smith & Nephew ElectroThermal Arthroscopy System (EAS) is the most complete RF system on the market today. With the launch of the Saphyre bipolar ablation line of probes, Smith & Nephew has the ability to take a commanding lead in the marketplace. Smith & Nephew already is the leader in thermal modification of soft tissues with the Vulcan generator, and the Saphyre line has the potential to propel the entire Smith & Nephew product line into a market leadership position.

The following strategies are key to the success of the launch of the product line.

Strategy #1: Differentiate the Smith & Nephew EAS from all competitors.

Tactic: Be sure to investigate your customer's situation and usage of RF *before* pulling out the Saphyre probe. When you understand their needs, clearly position and explain its benefits as part of the full Smith & Nephew system.

Tactic: Develop surgeon champions in your territory. Explore the interest from your most credible surgeons to support your sales efforts in other accounts. Often surgeons that are satisfied with our products will help to break the ice with other decision makers

Strategy #2: Leverage Smith & Nephew as a Sole Source Supplier

Tactic: Target existing accounts that are current Smith & Nephew resection customers AND are Vulcan accounts not using monopolar ablation.

Tactic: Emphasize full offering of RF arthroscopy products: Temperature control and ablation; wrist, ankle and hip applications; monopolar and bipolar modalities. This approach leverages sales of all probe types when the Saphyre products or the Vulcan Generator is introduced.

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Tactic: Leverage leadership in arthroscopy and RF technology at key events and training opportunities.
AANA, ESCA, AOSSM conferences
Orthopedic Learning Center courses

Tactic: Maximize incremental business using Saphyre probes.

NOTE:

We are specifically *not targeting* accounts where Smith & Nephew EAS monopolar ablation probes are used exclusively or extensively. We already have the business there! Let's use the launch of the Saphyre line to obtain new business. Do not cannibalize our existing monopolar probe volume. These customers are happy with their monopolar ablation products, and should be visited with Saphyre probes only if necessary.

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Saphyre Line Features and Benefits

The all-in-one Smith & Nephew ElectroThermal Arthroscopy System allows the surgeon to resect, contract, and coagulate using innovative monopolar and bipolar technology. Having all of these options available in one box simplifies purchasing and set-up while reducing inventory needs for the customer. Features and benefits covers both the Saphyre line and how it integrates with the Vulcan generator.

Features	Benefits
Bipolar ablation design	Teams aggressive ablation with enhanced, global coagulation performance
All-In-One System	Provides the customer with one system for tissue resection and contraction with a choice of monopolar or bipolar modalities
Innovative electrode design with notched face and energy directing flutes	Enhances ablation performance to maximize tissue effect, especially on "frond-like" tissue
"CoolBack" design with insulation on entire shaft except for exposed anterior return electrode	Focuses ablation effect toward active electrode where it is needed, while the insulation on the posterior portion of the shaft minimizes inadvertent damage to collateral tissue
Integrated Cable	Ensures easy connection with Vulcan generator. Eliminates handling of reusable cables
Color coded shaft insulation and connectors for each family of probes	Allows for easy recognition of and differentiation between each probe type
Field-Upgradable System	Allows for updating Vulcan generators in the field so the customer always has the latest technology available, with no downtime.
Suction with adjustable flow control	Improves visualization by reducing "snowy" arthroscopic field, removing small tissue particles and bubbles

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Ablation Market Segments and Technical Review

The RF arthroscopy market is founded on cutting and ablation applications, making up about 90% of all RF cases. Temperature control or tissue contraction markets comprise only about 10% of the RF procedures performed in today's market. The growth potential for both areas is enormous. This section reviews technical and clinical use of the Saphyre probes.

Technical Review

The Saphyre probe is an ablation probe intended to resect soft tissue and perform hemostasis (coagulate blood vessels). Like all ablation probes, Saphyre probes are intended to rapidly remove soft tissue to achieve a clinical result, such as reducing inflammatory agents, creating room for visualization in the joint space or gaining access to anatomical regions underneath the soft tissue.

Cutting and ablation is generally performed with high power levels, from 90 to 200 watts. Coagulation can be achieved with 30 to 60 watts (higher temperatures tend to ablate blood vessels not coagulate them to stop bleeding). The Vulcan software defaults to 120 watts for Cut, and 50 watts for Coag when a Saphyre probe is connected. Settings for both Cut and Coag can be manually adjusted between 5 and 160 watts for the Saphyre probes.

To use a Saphyre probe, the surgeon does not need to maintain full electrode contact on the tissue. This is different than the monopolar Ablator technique, where full electrode contact is necessary to achieve an arc. Saphyre probes may arc when activated at high power (120 watts or greater) in the conductive irrigant. This is very helpful for removing frond-like or wispy tissue.

Additionally, bleeders can be addressed by moving the Saphyre probe in the region of the open vessel, versus actually making direct contact with the bleeder as needed with the monopolar Ablator. This is because a bipolar probe creates a pocket of heat around the active electrode. It may only be necessary to get close to the bleeder rather than touch it directly.

The return electrode on the distal shaft does heat up when energy is activated. It will not get as hot as the active electrode (tip), but it may be hot enough to thermally damage tissue. This effect is common to all bipolar RF arthroscopy probes. It is the reason that Saphyre probe was designed with an insulated back-side on the distal shaft. Unwanted tissue damage can occur when the return electrode touches tissue that is not part of the treatment area. Protecting the patient and giving the doctor the safest features is one of the great advantages of the Saphyre probe design.

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A conductive irrigation solution, such as Lactated Ringers or sterile saline, is required for arthroscopic electrosurgical procedures. Sterile water should not be used. In addition to creating an electrolytic imbalance in the joint tissue, sterile water will inhibit the arcing and heating that is required to electrosurgically remove tissue.

A grounding pad (return electrode pad) is not required for use with the Saphyre probe. However, if the surgeon will be using another Vulcan probe, such as a TAC or Ligament Chisel, a grounding pad will need to be placed on the patient during the procedural set up. [Refer to Good Practices for Ground Pad Placement document available from Customer Service.] If a grounding pad connects the patient to the Vulcan and a Saphyre probe is used, there is no conflict. Vulcan recognizes that the Saphyre probe is a bipolar probe and the software disables the grounding pad and NEM circuits. In other words, in bipolar mode the Vulcan ignores an attached ground pad and the NEM light will be blank.

Saphyre probes are not malleable. One reason is that the return electrode or its power wire may be damaged if bent in the distal portion. This could render the probe non-functional in the bipolar mode. Also, there is a risk of occluding or crimping the suction tube inside the shaft of a suction probe. If this were to happen, visibility could be greatly reduced and fluid trapped in the distal portion of the probe could become heated.

Applications

Regulatory advisement

Physicians use RF ablation in a variety of procedures. Saphyre probes cannot be marketed for use in any specific application or specific joint at this time because of the level of regulatory clearance currently on file. Monopolar Ablators can be marketed for specific applications and joints.

The review of applications that follows is typical of the RF ablation market in general. Hemostasis may be performed in all of these and many other arthroscopic procedures.

Shoulder applications

Common ablation uses in the shoulder include:

- Subacromial decompression
Surgeons ablate the soft tissue on a bone spur under the acromion. The spur is then burred down to relieve compressive pain. This is the most common arthroscopic procedure using RF ablation.

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- Excision of scar tissue
- Debridement of the rotator cuff
- Capsular release
Cutting of the capsular tissue to open up the joint

Knee applications

Common ablation uses in the knee include:

- Excision of torn anterior cruciate ligament (ACL) or posterior cruciate ligament (PCL)
 - Notchplasty
Debridement of the ACL or PCL notch after ligament removal.
Cleans out the ligament stump in preparation for ligament repair
 - Synovectomy
Removal of inflamed synovial lining
 - Partial meniscectomy
Sculpting or smoothing of torn meniscal cartilage to preserve remaining healthy tissue. RF ablation will generally not remove or cut away significant sections of meniscus
- ❖ Ablation is NOT recommended for use on articular or hyaline cartilage, such as in femoral or patellar chondroplasty. Preservation of living chondrocytes in articular cartilage is critically important. Ablation may cause extensive damage to this tissue. Temperature-controlled or mechanical tissue effects are much more superficial and thought to be less harmful.

Ankle applications

Some surgeons will use standard-sized probes for ankle procedures. Others may choose only small diameter probes like the monopolar Ablator 2mm or the monopolar Micro Ablator. Common ablation uses in the ankle include:

- Excision of scar tissue
- Synovectomy
Removal of inflamed synovial lining
- Debridement of tendons or ligaments

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A 23175

New 3.51 Software for Saphyre

The Vulcan generator is a software-driven system that allows us to perform field upgrades. This helps to enhance our competitive edge and keep Vulcan performance completely up-to-date in a cost-effective manner. The upgrades are performed using a PCMCIA card that takes only a few minutes for our field representatives to install. The upgrade process gives you another reason to be in front of your customers to discuss the Smith & Nephew EAS system – and an opportunity to turn this call into a sale!

In the past, ORATEC has had optional upgrades at times that allowed customers the choice to include some additional features. Other upgrades are mandatory; in these cases the software upgrade must be implemented on all Vulcan units to provide for some feature or performance factor that we want to make available to all customers.

Smith & Nephew is pleased to announce the release of version 3.51 software for upgrading the Vulcan generator. Version 3.51 software has many value-added benefits including the ability to use the Saphyre bipolar probes.

This upgrade is mandatory so every generator in the field must be upgraded by the distributorship.

What 3.51 software does for your customer:

1. Auto-probe recognition allows the system to automatically recognize the Saphyre models of probes
 - Sets the correct Preset for each probe type.
 - Automatically changes the generator to bipolar mode ("Bipolar" will be illuminated).
2. Updates default settings for Ligament Chisels to 90W Cut and 40W Coag (previously was 80W Cut and 40W coag). (Also available in 3.50 software)
3. Adds a safety feature for low impedance, monopolar cutting conditions. When the generator detects impedance below 400 ohms for a continuous 5 seconds, power is rapidly cycled from full to no power until the impedance rises above 400 ohms. This limits the dispersed current to minimize undetected, incidental heating. (Also available in 3.50 software)

Mandatory Upgrade Implementation:

Software upgrade training packets will be sent to each Smith & Nephew Endoscopy field representative including upgrade instructions, reporting instructions, and return instructions.

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A 23176

An allotment of 3.51 software cards will be sent to the Distribution Executive main office, to be divvied up appropriately amongst the field reps. As the software cards are used up and when reporting information has been returned to Smith & Nephew, an additional quantity of software cards may be requested by the distributorship until all upgrades have been completed throughout the field. No software cards will be sent if reporting information is not received. A detailed tracking program is maintained in-house to ensure that all generators in your territory are upgraded.

How to upgrade software (see the "Upgrading the Vulcan Generator" attached for detailed instructions):

- 1) Turn off power to the generator.
- 2) Locate the plate and screws that protect the slot for the software card (located at the bottom, right hand corner of the box).
- 3) Unscrew the plate protecting the software card slot.
- 4) If an old software card is in the slot, push the black button located at the left of the card to eject the old software card (ignore this step if no card is present in the slot). Insert the new card into the slot with the label facing down. Make sure the card is securely inserted or the generator will not function.
- 5) Replace the plate protecting the slot for the software card.
- 6) Turn on the generator and check the LCD screen to make sure that 3.51 software version is displayed.
- 7) The upgrade is now complete.
- 8) Complete your paperwork with log account name, date, serial number, etc.
- 9) Give a copy of the 3.51 software preset table to the customer.
- 10) Ship any old software cards to Smith & Nephew at the address below.
These cards are valuable!

Remember: Once 3.51 software is installed, when using a Saphyre probe check to make sure the box is showing bipolar mode and the correct preset is displayed (Preset 17: 120 cut, 50 coag).

Important Contacts:

- For problems upgrading the software, contact Joan McCreary at 888-996-1996 immediately.
- For additional 3.51 software card shipments, contact Customer Service at 888-996-1996
- Ship old/unused software cards to:
Monica Allgood
Smith & Nephew Endoscopy
3700 Haven Court
Menlo Park, CA 94025

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Upgrading the Vulcan Generator

Step 1

Prior to upgrading the software:

Turn on the generator and record the software version.

Record the unit's serial number and location.

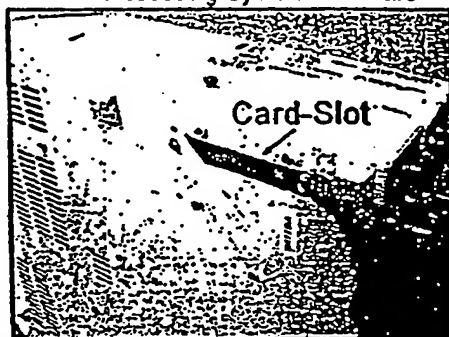
Turn off and unplug the generator.

Step 2

Remove screws from bottom of Vulcan Generator unit to access the card slot.

You will need a Phillips screwdriver.

Accessing System Software



Step 3

If a card is present, push the eject button at the front side of the slot. The card will pop free, then remove it.

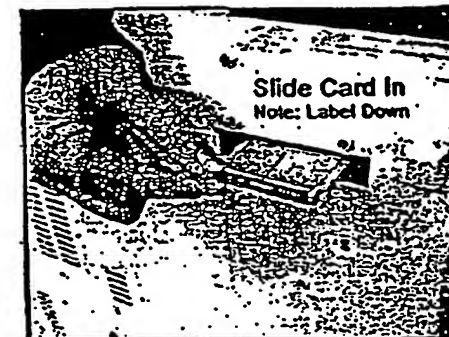
If a card is not present, go to Step 4



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Step 4

Insert the new software card, with the label facing downward. When fully inserted, the card will lock into place. Leave the card in the slot.



Step 5

Once the new card is in the slot, close the card access door and tighten the screws.

Turn on the generator and confirm the display reads Software Version 3.51.

Complete your paperwork and move on to the next generator

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Competitive Overview

Parameter	ArthroCare	Mitek	Stryker	Linvatec	Smith & Nephew-ORATEC
Generator	System 2000	VAPR	Serfas	N/A	Vulcan
Market Share	51%	21%	1%	1%	26%
RF type	Bipolar	Bipolar	Bipolar	Monopolar	Monopolar and Bipolar
Probe groups	Ablation Small joint Shrinkage Suction	Ablation Small joint Shrinkage Suction	Ablation Small joint	Ablation Small joint	Ablation Small joint Shrinkage w/ temp. control Hip Suction
Probe group prices	Ablation-\$151 Small joint-\$151-156 Thermal modification-\$270 Suction-\$172	Ablation-\$149-161 Small joint-\$161 Thermal-\$199-205 Suction-\$154 Temp. Control-\$313	Ablation-\$165 Small joint	Ablation-\$85 Thermal modification	Ablation-\$129-151 Small joint-\$140-149 Temp. control-\$299 Hip-\$450-499
Features	<ul style="list-style-type: none"> Aggressive soft tissue resection Multiple tips Perceived large market share in ablation Hand control attachment 	<ul style="list-style-type: none"> Multiple tips Wide range of arthroscopic products Well known in orthopedic market TC Electrode monitors power output Has probe recognition 	<ul style="list-style-type: none"> Hand control Bendable probes Ability to bundle with other products Well known sales force 	<ul style="list-style-type: none"> Multiple probe tips Broad line of arthroscopic products Resection/ablation probe 	<ul style="list-style-type: none"> Very aggressive ablation performance All-in-one system Integrated cable Unique electrode design Wide range of arthroscopic repair and resection products

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A 23179

Parameter	ArthroCare	Mitek	Stryker	Linvatec	Smith & Nephew-ORATEC
Features, continued					<ul style="list-style-type: none"> • CoolBack design • Field-upgradable system • Multiple tips with malleable shafts • Temperature control • Many peer-reviewed articles that show safety and efficacy
Weaknesses	<ul style="list-style-type: none"> • No temp. control • Limited and nonspecific power settings • Inadvertent heating of collateral tissue • Reaches very high temperatures • Very few probes are malleable • No probe recognition • Autoclavable cables • Generator not field upgradable 	<ul style="list-style-type: none"> • Average tissue reaction in both temp control and ablation • Not aggressive enough for many surgeons • Temperature control is questionable • Very few malleable probes • Autoclavable cables • Limited power settings • Generator not field upgradable 	<ul style="list-style-type: none"> • No temp. control • No scientific documentation • Average performance • Small offering of probe tips • No probe recognition • Autoclavable cable • Limited power settings • Generator not field upgradable 	<ul style="list-style-type: none"> • Average performance • Limited probe tips • No temp. control • Autoclavable cables • No proprietary generator • No scientific data 	<ul style="list-style-type: none"> • Vulcan system has been known as the "monopolar system"

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A 23180

S + N RF Probe Possible Cross Reference

4/15/2002
R. Quinn

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Note: Mitek's current price list is dated 2001 but prices have been verified on 2-04-02 as current

Mitek	Mitek description	S + N	Smith & Nephew Description	Current Price	Current Price
225252	VAPR TC Electrode (2.3mm)	921001	TAC-S	313	299
N/A	No comparison	921006	TAC-S Angled	N/A	299
N/A	No comparison	921013	TAC-G II	N/A	299
225301	Side Effect Electrode (3.5 mm)	925001	Saphyre 90° Bipolar Ablator	149	151
225301	Side Effect Electrode (3.5 mm)	920001	Ablator 90°, Monopolar	149	129
N/A	No comparison	920007	Ablator 90° HP	N/A	129
N/A	No comparison	923002	Ligament Chisel, Angled	N/A	115
N/A	No comparison	923001	Ligament Chisel, Straight	N/A	115
225302	Angled Side Effect Electrode (21°, 3.5 mm)	920001	Ablator 90°	155	129
225303	End Effect Electrode (3.5 mm)	920002	Ablator 30°	148	129
225304	Angled End Effect Electrode (21°, 3.5 mm)	920002	Ablator 30°	155	129
225305	90° Hook Electrode (3.5 mm)	923004	Ablator Hook	144	115
N/A	No comparison	923003	Lip, Chisel, Cvd.	N/A	115
225312	Flex, Side Effect Electrode (3.5mm)	920001	Ablator 90°	157	129
225314	Flex End Effect Electrode (3.5mm)	920002	Ablator 30° or Ablator 60° 920003	157	129
225350	90 deg. Suction Electrode (3.5mm)	925011	Saphyre 90° Ablator, w/Suction	164	172
225350	90 deg. Suction Electrode (3.5mm)	920011	Ablator-S, 90°	164	159
N/A	No comparison	925003	Bipolar Ablation Probe, 60°	N/A	151
N/A	No comparison	925013	Bipolar Ablation Probe, 60° w/suction	N/A	172
N/A	No comparison	920003	Ablator 60°, Monopolar	N/A	129
N/A	No comparison	920013	Ablator-S, 60°	N/A	159
225201	2.3 Side Effect Electrode	923006	Micro Ligament Chisel, Curved	161	125
225202	2.3 End Effect Electrode	923005	Micro Ligament Chisel, Angled	152	125
225203	Wedge Electrode (21°, 2.3mm)	920023	Ablator 2.0mm, 60° Tip	152	139
N/A	No comparison	920014	Ablator 2.0mm, 60° Tip, w/Suction	N/A	159
N/A	No comparison	925007	Bipolar Ablation Probe 90°, High Profile	N/A	151
N/A	No comparison	925015	Epider Abl. Probe 90°, High Profile w/Suction	N/A	172
N/A	No comparison	920007	Ablator 90° High Profile	N/A	129
N/A	No comparison	920015	Ablator 90° High Profile-Suction	N/A	159

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A 23181

N/A	No comparison	923008	Micro Ligament Chisel, Hook	N/A	125
N/A	No comparison	913007	Eller Ligament Chisel	N/A	349
N/A	No comparison	911007	Eller TAC-S	N/A	499
N/A	No comparison	910014	Eller Ablator	N/A	349
225101	Thermal Side Effect Electrode (3.5 mm)*	N/A	No direct comparison	199	See TAC-S as possible substitute
225112	Thermal Reversed Angled Side Effect Electrode (3.5 mm)*	N/A	No direct comparison	199	See TAC-S as possible substitute
225104	Thermal Angled End Effect Electrode (3.5 mm)*	N/A	No direct comparison	199	See TAC-S as possible substitute
225322	Thermal Flexible Side Effect Electrode (3.5mm)	N/A	No direct comparison	205	See TAC-S as possible substitute
225324	Thermal Flexible and effect Electrode (3.5mm)	N/A	No direct comparison	205	See TAC-S as possible substitute

* Although described as a "thermal electrode" these products do not provide active temperature measurement or automatic power control to maintain a specific treatment temperature.

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A 23182

S + N - ArthroCare Possible Cross Reference

4/19/2002
R. Griffin

NOTE: ArthroCare has stopped publishing a quantity discount for 10+ probe purchases, a discount may be in effect but is not published as part of their pricing. Always get verification of competitive prices.

Catalog I	ArthroCare Description	Cal. No.	Smith & Nephew Description	Jan. 02 ArthroCare List Price	Level A S + N List Price
A 1326-01	2.5mm 90° Right Angle	920001	Vulcan Ablator 90, 3.0mm	151	129
A 1330-01	3.0mm 90° Right Angle	920001	Vulcan Ablator 90, 3.0mm	151	129
A 1335-013	3.5mm 90° Right Angle	920007	Vulcan Ablator 90 HP	151	129
A 1338 01	3.6mm 90° Lo Fro Right Angle	920001	Vulcan Ablator 90, 3.0mm	151	129
A 1345-01	4.5mm 90° Eliminator	920001	Vulcan Ablator 90, 3.0mm	151	129
A 3525-01	2.5mm 60° dome	920003	Vulcan Ablator 60, 3.0mm	151	129
A 3525-01	2.5mm 30° dome	920002	Vulcan Ablator 30, 3.0mm	151	129
A 3530-01	3.0mm 60° dome	920003	Vulcan Ablator 60, 3.0mm	151	129
A 2430-01	3.0mm 45° bevel	921003	Vulcan Ablator 60, 3.0mm	151	129
A 2530-01	3.0mm 60° bevel	920002	Vulcan Ablator 30, 3.0mm	151	129
A 2630-03	3.0mm 30° bevel	920023	Vulcan 2mm Ablator Probe	N/A	139
N/A	2.0mm 60° Ablator				
Thermal Probes (note: Acare does not control power or temperature)					
A 1730-01	3.0mm CAP Sure	921008	Vulcan TAC-S Probe	270	299
A 1830-01	CAP Sure 30	921008	Vulcan TAC-S Probe	270	299
A 1720-01	MicroCAPS	921004	Micro TAC-S	270	299
N/A	N/A	921009	Micro TAC-S, Angled	N/A	299
N/A	N/A	921008	Vulcan TAC-S Angled	N/A	299
N/A	N/A	921003	Vulcan TAC-G II Probe	N/A	299
N/A	N/A	921002	Vulcan MiniTAC Probe	N/A	299
N/A	N/A	921004	Vulcan MicroTAC-S	N/A	299
N/A	N/A	921009	Vulcan MicroTAC-S, Angled	N/A	299
Small Joint Probes-Ablation/Resection					
A 2723-01	2.3mm 25° bevel	923005	Vulcan Micro Ligament Chisel, Ang.	151	125
A 2823-01	2.3mm 35° bevel	920006	Vulcan Micro Ablator 2.0mm, 60°	151	139
A 1116-01	Microblator	923006	Vulcan Micro Ligament Chisel, Hook	156	125
N/A	N/A	923006	Vulcan Micro Ligament Chisel, Cvd.	N/A	125
Hip Arthroscopy					
N/A	N/A	913007	Vulcan Effect Ligament Chisel	N/A	349
N/A	N/A	910014	Vulcan Effect Ablator	N/A	349

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A 23183

N/A	N/A	911007	Vulcan Ellex TAC-S	N/A	499
AS 4730-01	MultiVac XL	910011	Vulcan Ablator-S 90°	165	159
A 4030-01	Cutting Probes	923003	Ligament Chisel, CVD	151	115
A 4330-01	CoBlade	923004	Ligament Chisel, Hook	151	115
A 8 2630-01	Suction Probes	920013	Vulcan Ablator-S, 60°, Monopolar	172	159
AS 3730-01	3.0mm 60° CoVac	925013	Saphyre Bipolar-S, 60°	172	172
AS 1335-01	3.0mm 70° CoVac	920013	Vulcan Ablator-S, 60°, Monopolar	172	159
AS 1337-01	3.0mm 90° Turbo Vac	925013	Saphyre Bipolar-S, 60°	172	172
AS 4130-01	3.5mm 90° Turbo Vac HP	920011	Vulcan Ablator-S 90° High Profile, Monopolar	172	159
AS 4630-01	MultiVac TriStar 15	920015	Vulcan Ablator-S 90° High Profile	172	172
AS 6840-01	MultiVac TriStar 50	925007	Saphyre Bipolar-S, High Profile	172	159
	Titan 60	925013	Saphyre Bipolar-S, 60°	172	172
		920013	Vulcan Ablator-S, 60°, Monopolar	172	159
		925013	Saphyre Bipolar-S, 60°	172	172
		910013	Vulcan Ablator-S, 60°	172	159
		925013	Saphyre Bipolar-S, 60°	172	172

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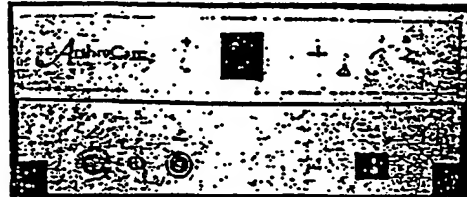
Competitive Review-Arthrocare

Arthrocare System 2000

Features:

- Single display for ablation and coagulation
- Bipolar system
- Ablation settings 1-9. Settings correspond to these powers:

1-40W
2-50W
3-80W
4-100W
5-125W
6-160W
7-200W
8-240W
9-280W



- ArthroWand Probes
 - Over 25 probe tip styles including ablation, shrinkage, small joint, and suction (ex: MultiVac, CoVac, Razor, Eliminator, CAPSure, Saber, etc.)
 - 90° ablation probes represent the majority of probe sales
- Perceived as having the largest RF market share in ablation business
- Multi-electrode ablation design
- Autoclavable cable
- Foot and hand controls available



Pricing:

System Component	Description	Price
Arthrocare System 2000 (includes Generator, Cable, Foot Control, Power Cord, and User's Manual)	Bipolar generator designed for use with ArthroWand for resection, ablation, and coagulation of soft tissue. Includes nine presets for different probes.	\$7,500
ArthroWands	A wide range of probes are available for ablation, coagulation, and modification of soft tissue	Ablation-\$151 Small Joint-\$151-156 "Shrinkage"-\$270 Suction-\$172

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Cable	To connect the ArthroWand to the System 2000	\$500
Power Cord	Connects the System 2000 to the power outlet	\$100
Probe Bender	Bends malleable probes	\$100
Foot Control	Provides control to the generator with ablation, coagulation, and ablate adjuster	\$750
Hand Switch Control	Same as foot control but accessible by hand	\$300
Cable O-ring	To ensure good connection with Wand and cable	\$10 (pack)

Strengths:

1. Aggressive soft tissue resection and coagulation: Very aggressive ablation and good coagulation reduces OR time for the surgeon.
2. Multiple tips allow access for many applications that include resection, coagulation, and modification of soft tissue.
3. Is the perceived leader in the ablation market, with a market perception of ArthroCare having aggressive ablation.
4. Hand and foot controls provide a convenient level of control for power settings and energy activation.

Weaknesses:

1. No temperature control to monitor depth of tissue effect that is very important for procedures such as capsulorraphy and chondroplasty.
2. Non-specific power settings deny the user a full understanding of the energy being applied.
3. Inadvertent heating of surrounding tissue due to concentric, uninsulated return electrode. Users may be confused by the multi-pin electrode configuration and mis-understand potential heating concerns.
4. Reaches very high temperatures, as seen in surgery with boiling saline (100°C) and tissue char (-270°C). Overheated fluid may inadvertently damage surrounding tissue in the joint or instrument portal.
5. Few malleable probe designs, limiting the ability to access hard-to-reach anatomy (such as posterior horn of the meniscus)

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6. No probe recognition, generator does not adjust to each probe for optimal performance, but instead needs circulatory staff to remember and/or adjust settings wasting valuable OR time.
7. Autoclavable cables that cause needless delay because of sterilization and bad connection caused by wear. ArthroCare typically charges for replacement cables.
8. Generator is not field upgradable possibly leading to down time for shipping or exchanging for a new generator.

Competitive Strategy:

1. With the addition of bipolar ablation, Vulcan now offers the best of both worlds: temperature control for temperature sensitive procedures and aggressive ablation to reduce procedure time.
2. Vulcan is also teamed with the widest variety of probes including ablation (monopolar and bipolar), temperature control, small joint, cutting, and hip probes.
3. With the versatile performance of the Vulcan generator and the scientific data to back its safety and efficacy, Smith & Nephew will be knocking away at Arthrocare's RF market share.
4. Sales representatives can use their wide range of Dyonics products to leverage the Smith & Nephew RF products, using its leadership position in the resection market to solidify the relationship.
5. Expose the differences in return electrode configuration between Saphyre probes and the ArthroCares.

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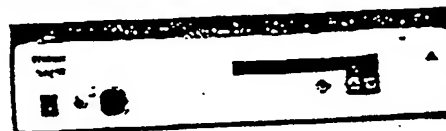
Competitive Review-Mitek

Mitek™ VAPR™ II (Ethicon Division of Johnson & Johnson)

VAPR II Generator

Features:

- Dual display for ablation and coagulation
- Bipolar system
- Programmable temperature settings
- Temperature Control Electrode
 - Uses thermistor to monitor temperature
 - Software is not as advanced as Vulcan in adjusting output for temperature control
- Multiple probe designs for different applications (see following chart for probes and defaults)
- Weak competitor in RF market
- Autoclavable cable
- Foot control



Pricing:

System Components	Description	Price
VAPR II	Bipolar generator designed for use with VAPR II electrodes for resection, ablation, and coagulation of soft tissue. Includes multiple default settings for various probes.	Not published
VAPR Electrodes	A wide range of electrodes are available for ablation, coagulation, and modification of soft tissue.	Ablation-\$149-161 Small Joint-\$161 Shrinkage-\$199-205 Suction-\$154 Temp. Control-\$313
VAPR Handpiece	Cable to connect the VAPR II to the electrode, recommended for 20 uses.	\$349
VAPR Footswitch	To energy delivery from	\$465

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	VAPR generator	
VAPR Power Cord	To connect the VAPR generator to a power outlet	\$117
VAPR Sterilization Tray	For sterilizing of reusable product	\$244

Strengths:

1. Multiple tips for a wide range of applications including resection, coagulation, and modification of soft tissue.
2. Wide range of orthopedic products to leverage relationship with customer.
3. Well-known name in the orthopedic market.
4. TC Electrode that monitors temperature for temperature-sensitive procedures.
5. Generator is programmable for probe-specific default settings

Weaknesses:

1. Average tissue response to electrodes, slowing down the procedure.
2. Limited availability in probe designs that allow access to hard-to-reach places.
3. Autoclavable cables that cause needless delay because of sterilization and faulty connections caused by wear.
4. Power settings are not refined with accurate temperature control to provide consistent performance.
5. Generator is not field-upgradable, possibly leading to down time for shipping or exchanging for a new generator.

Competitive Strategy:

1. The best way to combat the Mitek product is to show the complete package that we offer with the leading temperature control product on the market along with aggressive monopolar and bipolar ablation. No other company can offer that.
2. Team the all-in-one system with the leading resection products of Smith & Nephew and you have a winning combination. Even with Mitek's range of products, we provide the most comprehensive line of products with superior quality and service.
3. Make a clear distinction between Vulcan temperature control and VAPR temperature control. Vulcan uses a thermocouple to measure temperature at the probe tip and adjusts the power output 50 times a second! The Vulcan software also has other key technology built into the generator to optimize

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performance while keeping accurate temperature control. For example, ramping the power up quickly when the footpedal is depressed to reach the target temperature quickly, then backing off the power as the temperature is reached to maintain an even temperature level. This way the generator only delivers the minimum power needed to maintain tip temperature. Milek uses a thermistor to measure tip temperature and the software used in the VAPR generator is not as advanced as the Vulcan.

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Competitive Review-Stryker

SERFAS™ System

Features:

- Single display for cut with presets. Low, Medium or High settings for coag.
- Bipolar system
- Built-in troubleshooting guide with voice feedback
- SERFAS Probes
 - Seven probe styles for ablation including two small joint probes
 - Malleable up to 45°
 - Flow-Port™ to reduce bubble size (no suction)
- Hand and foot controls
- Autoclavable cable

Pricing:

Ablation probes-\$165

Strengths:

1. Hand and foot controls to allow the surgeon to adjust the settings easily.
2. Bendable probes to allow better access to joints.
3. Ability to bundle the probes with other arthroscopy products.
4. Well-known sales force.
5. Troubleshooting guide built into system.

Weaknesses:

1. No temperature control probes for contraction of soft tissue or cartilage applications (using bipolar ablation on cartilage has been shown to have a much greater depth of penetration than monopolar TAC-C II probe).
2. No scientific data on tissue effect.
3. Average ablation performance.
4. Only seven probe styles, limiting applications and choices for the surgeon.
5. No suction probes to reduce cloudy or "snowy" field.
6. No probe recognition, the circulator must adjust the settings.
7. Limited power settings for the surgeon, reducing versatility of probes.
8. Autoclavable cables that cause needless OR delay because of sterilization and bad connections caused by wear.

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9. Generator is not field-upgradable, possibly leading to down time for shipping or exchanging for a new generator.
10. Late entry to RF market with very small market share.

Competitive Strategy:

1. SERFAS is no contest for the comprehensive Smith & Nephew line of probes, which has over 25 probe styles that include ablation, temperature control, monopolar, and bipolar capabilities.
2. Point out Vulcan's extensive data to show tissue effect compared to Stryker's lack of data.
3. Use your superior line of Smith & Nephew products including the #1 resection products in the business to combat Stryker's bundling.
4. Vulcan's comprehensive, easy-to-use system with integrated cable and auto-probe recognition gives the physician a user-friendly, flexible choice compared to the SERFAS. Vulcan also has live 24 hour support for troubleshooting needs.

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Competitive Review-Linvatec

Generator and Probes:

- May be used with many standard monopolar electro-surgical generator (ex: Valleylab, Conmed)
- Attaches to bovie pencil handle
- Variety of probes for ablation, cutting, and coagulation (UltrAblator™, Trident combination ablator/shaver, Heatwave™, Concept®, ESA)
- Uses "coag" mode for ablation, "cut" mode for coagulation, and "cut" mode for capsular shift

Pricing:

System Component	Description	Price
Generator	Produces power output to run probes. Many standard electro-surgical generators work.	Relies on having an electro-surgical generator in the facility. Prices vary.
Electrosurgical Product Line	Includes a limited mix of probe tips for ablation, coagulation, cutting, and capsular shifts	Ablation-\$85 Shrinkage-unknown
Grounding Pad	Needed for use with electro-surgical generators	-\$6-10

Strengths:

1. Multiple probe tips.
2. Broad line of arthroscopic products.
3. A unique shaver/ablation probe called Trident.
4. Trident incorporates suction through the shaver blade opening.

Weaknesses:

1. Average performance.
2. Limited probe tips that may not fit surgeon preference.
3. No temperature control to control depth of penetration during capsular shifts.
4. Has to rely on functionality with other manufacturers electro-surgical generator for probes to work.

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5. Trident's suction is not at the point of ablation, which may inhibit removal of bubbles from the point of energy delivery.
6. Autoclavable cables that may delay surgery due to bad connections or need for sterilization.
7. No scientific data to show tissue effect.
8. Most probes are very similar to bovie pencil that the accounts already have.

Competitive Advantage:

1. The best way to combat Linvatec is to ask the surgeon to use the product (especially works for the Trident). Reports from the field say it has mediocre ablation and coagulation performance compared to Vulcan's monopolar or bipolar ablation, and coagulation doesn't stand a chance. The surgeon probably won't want to use it again.
2. If the surgeon is motivated to use Linvatec because of bundling programs even though performance isn't great, use our superior line of products to offer a better value to the surgeon. We have the tools available with the quality and performance they want. And we can offer bundling with Dyonics equipment, too.
3. They have no temperature control for capsular shift procedures to control healing of tissue, we do. This is key in capsular shift procedures for optimal outcomes.
4. We have extensive data that shows tissue effect with Vulcan products; point out Linvatec's lack of data.
5. The inability to customize setting and limited probe tips severely limits the surgeons' choices with the Linvatec line. Vulcan is able to give the surgeon a wide variety of probe choices with the most up-to-date software for each probe. The Vulcan system can do it all.

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Competitive Review: Probing Questions

Use the following probing questions to get your customer thinking about the advantages that the Saphyre probe and Smith & Nephew EAS can offer. Questions can lead your doctor to the make the purchasing decision on his/her own.

1. What factors are important to you in selecting an ablation probe? If our product could meet your objectives, would you evaluate it?
2. Would you see an advantage to using a sole source supplier for arthroscopic resection? Would having to work with one sales representative ease congestion and disruptions in the OR?
3. Is there ever a problem with locating or using re-usable cable in the OR? Would eliminating a piece of equipment help to control OR efficiency?
4. Are you satisfied with the level of control that you obtain with your current bipolar product?
5. Have you ever wanted to switch between ablation and temperature control probes in a case, but this was difficult because you use two different vendors with different generators?
6. How often is the return electrode of your current bipolar ablation probe outside of your field of view while you are ablating?
7. Have you ever wondered what is happening to the tissue that the return electrode is touching while you are ablating?

Be prepared to handle objections from the surgeon. Here are some examples.

1. Doctor: I'm happy with my current bipolar probe's ablation performance. Why should I switch to your bipolar probe?

Rep: Doctor, let me show you a unique feature on the Saphyre product. The return electrode is here, just below the tip. Notice how the electrode wraps around the front and sides, but is insulated on the back, protecting adjacent tissue. Now look at the bipolar probe you are using. The return electrode is also just below the tip, but it wraps around the entire shaft. This can expose tissue like the rotator cuff to a very hot surface when ablating in the subacromial space.

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2. Doc: My surgery center is very cost-conscious. I'm not sure I like the pricing you're offering.

Rep: Doctor, I can offer your hospital a nice pricing and service advantage if you choose Smith & Nephew as your sole source provider of resection products. Since you're already a great Dyonics shaver customer, it would be a natural to bring Vulcan and Saphyre products into your surgery center. From a cost perspective, you have a fantastic opportunity here.

3. Doc: I don't use RF ablation very much. Why should I change my current practice?

Rep: What is your current method for resection procedures? If you use Dyonics equipment and you are happy, there's no reason to change. However, Smith & Nephew now offers an extensive line of RF arthroscopy probes for a variety of applications. Your colleagues may also benefit from the small joint and hip probes. I would be happy to contact them and let them know about this new opportunity.

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The Sales Process

Using the Vulcan customer list and our targeted launch strategy for the Saphyre line, it should be relatively straightforward for you to identify the appropriate clinical decision makers to approach with Saphyre probes. It will be very important for you to avoid simply pulling Saphyre probes out of the bag and showing it off. Use your selling skills to gain an understanding of your customer's needs and objectives relative to RF systems before you actually present the Smith & Nephew EAS and Saphyre probes.

Please don't forget that each OR has a variety of decision makers, including the surgeon, nurses, OR supervisors and purchasing personnel. Position yourself as a resource with all of these parties to maximize your influence during the sales process.

The outline below walks through an effective sales process that may transpire on one visit or over several calls on this customer. The bullet points with quotes will give you some examples of useful lead-ins or wording that may be helpful to you. Other lines of questioning may be appropriate for your customers. You can use the following structures with any of the selling strategies outlined earlier in this Sales Guide.

Opening the Sales Call

- ❖ Ask questions to investigate whether this is an appropriate time to dive into the topic of RF.
- ❖ Position the current sales call to gain the customer's attention.
 - > "When I was in last week you mentioned that you would be interested in discussing RF in arthroscopy with me, at some point in the future. Would this be a good time for that?"
 - > "Over the past few visits, you and your staff have expressed concern over the increasing amount of equipment and confusion amongst the OR staff over having different systems for RF. May we discuss this further?"

Focus on the Customer's Situation

- ❖ Begin to focus your customer on the topic that you plan to discuss.
- ❖ Probe the current situation and methods used by your customer further.
- ❖ Use questions to uncover your customer's thinking and feeling!

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- > "I've noticed that you have more than one RF arthroscopy system here in the OR. Why is that?"
- > "Bring me up to date on your use of RF in cases here at Mercy. How has RF been incorporated into your practice?"

Explore Your Customer's Problems and Objectives

- ❖ Follow the issues your customer brings up during your discussion of the current situation.
 - ❖ Structure questions to explore problem areas that we expect to be occurring.
 - ❖ Questions also can reveal the objectives your customer may have to resolve current problems.
- > "Have you ever had a case delayed because a circulator was not familiar with the various RF generators in the OR?"
 - > "How have you responded when the connection cable between RF probe and the generator is not ready to go or is not in the room?"

Investigate and Reveal the Implications

- ❖ Now that you have an understanding of some of your customer's problems, formulate questions to reveal the underlying implications.
 - ❖ The issues uncovered by exploring problem implications help to expose the problem further – making it more urgent for the customer to act to solve the problem.
 - ❖ Your questions can reveal problem implications that Vulcan and Saphyre products can clearly solve!
- > "Having multiple RF systems here at Mercy does seem difficult. How have these delays affected your practice?"
 - > "OK, so your staff is tired of keeping up with all of the connection cables. How have the connection cable problems affected your use of RF in these cases?"

Develop Your Customer's Needs

- ❖ Use the problems and implications you've uncovered to develop a customer need that the Smith & Nephew EAS can resolve.

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- ❖ Ask questions that will reveal a need-payoff that Vulcan can provide.
- ❖ Begin to position your product offering as the solution to your customer's needs!

- > "Dr., would it be valuable to you to consolidate all RF use in one system? If I can show you that the Vulcan generator can excel at both temperature control and ablation, would you be willing to consider consolidating your RF usage?"
- > "Would you be interested in evaluating a system that eliminates the connection cables? What would you do with an ablation system that eliminated the connection cables?"

Ask for the Order!

- ❖ By following the sales process outlined above, you now have the customer in position to ask for an appropriate order or commitment.
- > "You already have the Vulcan generator here in your OR, let me bring in a sample ablation probe for you to evaluate during your next case. How about tomorrow?"
- > "You and your staff will love the Integrated Cable probes. When is your next case that will use RF ablation, and I'll be here with some evaluation probes?"

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Selling Tools and Resources

Pricing

See the Price List in the Collateral Materials Section.

Our price schedule for the Saphyre line places it in direct competition with ArthroCare and Mitek. With the features and benefits offered by the Saphyre line and the Vulcan generator, you should not have a large pricing hurdle to overcome. The key to success with this product is to sell the system and its features and benefits!

Discounting:

There is no standard discount available for Saphyre products.

Please review the attached price list and be ready to share this information with your customers.

Customer Targets

We are providing your distributor executive's office with information about current Vulcan customers that use our temperature control (TAC) probes, but do not order monopolar ablation products. These customers will form your top-priority account group. All of these customers have Vulcan generators in place and nearly all of them can be expected to have substantial volume in ablation probes.

The accounts on this report will be your top priority!

Saphyre Line Launch Roll-out

Each sales agent will receive four demo probes after the Knowledge Assessment is returned (enclosed). Smith & Nephew sales management will conduct frequent reviews of the Saphyre probe sales to ensure that appropriate accounts are being targeted and that monopolar ablation accounts are not cannibalized.

Saphyre Line In-service

See the Saphyre probe Instruction for Use (IFU) for more details.

❖ Ordering Information

- Order Saphyre Bipolar ablation products using the Smith & Nephew West Coast Customer Service line: 888-996-1996
- Be sure to specify model number or complete description and quantity for each item ordered.

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❖ Identify product and packaging

- Identify the packages containing Saphyre bipolar probes by:
 - > Gray color band on labels (vs. black for monopolar ablation)
 - > Label says "Saphyre"
 - > Model numbers: 925XXX
- Identify the product after opening the package by:
 - > Gray color insulation on probe shaft.

❖ Pre-procedure prep issues

- Prior to any procedure using Saphyre probes, the software of the Vulcan generator must be upgraded to version 3.51 or higher. The current software version of each Vulcan generator is displayed in the LCD message window when the generator is first powered up. A Vulcan with any software revision prior to 3.50 will not operate a Saphyre ablation probe.
- The Vulcan generator should be placed in a location close enough to allow probe connection (usually within 10 feet of the table).
- If it is possible that more than one probe will be used by the surgeon, or it is unclear which probe tip style will be used, make sure all of the appropriate probes are available in the room before the case begins.
- If the case has a chance of including the use of temperature control (TAC) probes or other monopolar probes, apply a Valley Lab grounding pad (split-pad return electrode) to the patient before draping the patient.
- The Saphyre bipolar ablation probes require the use of a conductive irrigation solution. Saline or Lactated Ringers solutions are good choices.

❖ Probe selection

- Tip configuration – the Saphyre line is available in 3 tip configurations:
 - 90-degree
 - 90-degree high profile
 - 60-degree
- Suction vs. non-suction – each Saphyre tip configuration is available in a non-suction model and suction model.
- Each surgeon will determine which model to use based upon the patient's anatomy, type of procedure and personal preference.

❖ Connection to generator

- The scrub tech in the sterile field can remove the clips that bundle the integrated cable of the Saphyre probe.
- The scrub tech passes the connector-end of the integrated cable to the circulator outside the sterile field.

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- The circulator connects the Saphyre probe cable to the Vulcan and turns the power on.
- That's it! The Vulcan generator will recognize that a Saphyre probe has been attached and set the appropriate operating parameters (pre-sets). The system is now ready to operate!

❖ Saphyre probe use tips/techniques

- NO Bending of probe shaft - Saphyre probe shafts are not malleable. The probe bender should not be used to modify the shaft shape.
- The surgeon may ask for the power levels to be adjusted during the case. Using a Saphyre probe, the Vulcan generator may be manually adjusted between 5 and 160 watts for both Cut and Coag modes.
- Care should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft. While it will not be as hot as the active electrode at the distal tip, the return electrode may become heated. For this reason, it is important to avoid inadvertent contact with tissue adjacent to the operative site.
- Full tissue contact may not be required during Cut or Coag applications. Saphyre probes may perform to the surgeon's clinical requirements when the probe tip is in close proximity to the tissue.
- Power delivery to the probe when the probe is not in tissue proximity (that is, foot pedal activation when not actively ablating or coagulating) risks increasing the temperature of the fluid in the joint. Be careful to terminate power delivery and to increase flush rate when possible.

❖ Probe disconnection and disposal

- When use of the probe is complete, disconnect the integrated cable at the Vulcan generator.
- Discard the entire probe with its cable. Usually a contaminated sharps container is an appropriate disposal container.

Please see the Saphyre probe Instruction for Use (IFU) for more details.

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From: Joan McCreary [jmcCreary@oratec.com]
Sent: Wednesday, May 01, 2002 11:19 AM
To: Peggy Greene
Subject: Saphyre collateral materials

Joan McCreary
Product Manager, Anthroscopy
Smith + Nephew, formerly ORATEC Interventions, Inc.
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Tel. 650-687-2620
Fax. 650-368-9534

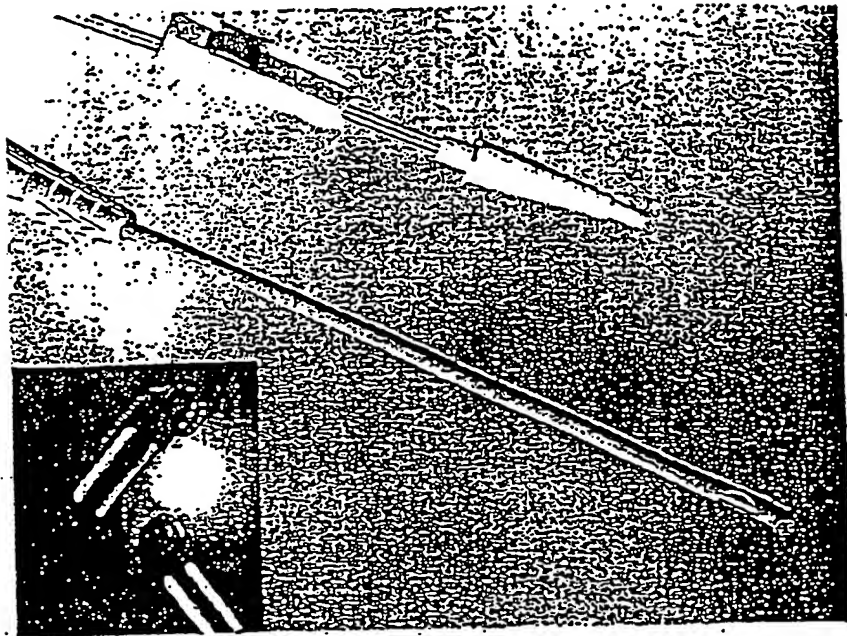
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6/20/2002

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Saphyre™ Bipolar Ablation Probes



CoolBack™ insulated shaft

60°, 90° and 90° high profile tips in
suction and non-suction styles

Jewel-cut electrode for rapid
ablation and precise coagulation

Integrated cable simplifies O.R. setup

Section regulator provides adjustable
bow control for excellent visibility

Bipolar Ablation with Unique Features for Performance and Convenience

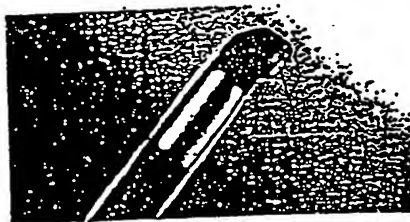
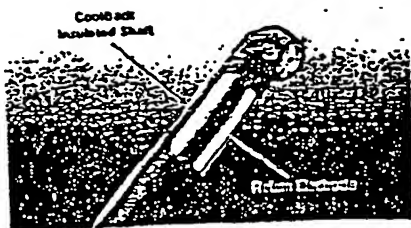
Saphyre™ Bipolar Ablation Probes offer a new standard for tissue removal. The jewel-cut notched electrode directs energy where it is needed to maximize tissue effect. The result is a larger area of tissue effect with rapid ablation. Saphyre probes incorporate the CoolBack™ shaft design, which protects adjacent tissue by not exposing the return electrode on the posterior shaft. As with all Smith & Nephew probes, the Saphyre has an integrated cable which takes the cable resterilization and storage off the Q.R. checklist.

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CoolBack™ shaft insulates collateral tissue on both suction and non-suction styles

Saphyre™ Bipolar Ablation Probes

Ordering Information

REF	Smith & Nephew REF	Description
923001	7209444	Bipolar Ablation Probe, 90°
923011	7209443	Bipolar Ablation Probe, 90° with Suction
923003	7209445	Bipolar Ablation Probe, 60°
923013	7209442	Bipolar Ablation Probe, 60° with Suction
923007	7209444	Bipolar Ablation Probe, 90° High Profile
923015	7209441	Bipolar Ablation Probe, 90° High Profile with Suction

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Smith+Nephew

www.endoscopy1.com

Smith & Nephew, Inc., Endoscopy Division
Menlo Park, CA 94025 U.S.A.
Telephone: 650-369-9904 • Fax: 650-369-9913
U.S. Customer Service: 1-888-996-1996
International Customer Service: +1-650-369-9904

Outside the U.S., please contact an authorized representative of Smith & Nephew.

For consistent, repeatable ablation results, choose Saphyre Bipolar Ablation Probes—only from Smith & Nephew, a world leader in technique innovation for endoscopy. Our strategic intent is to be: *The* choice of surgeons worldwide for surgical techniques that reduce trauma and pain to the patient, reduce cost to the healthcare system, and provide better outcomes for surgeons. Please let us know how we can help you.

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U.S. Hospital Price List
Smith & Nephew ElectroThermal® Arthroscopy System (EAS®)
Effective 04/24/2002

Catalog #	Probes with Integrated Cable	Unit Price
921001	TAC™ S	\$299
921008	TAC-S Angled	\$299
921013	TAC-C II	\$299
923001	Ligament Chisel™ Straight	\$115
923002	Ligament Chisel - Angled	\$115
923003	Ligament Chisel - Curved	\$115
923004	Ligament Chisel - Hook	\$115
920001	Ablator™ 90°, 3mm	\$129
920002	Ablator, 30°, 3mm	\$129
920003	Ablator, 60°, 3mm	\$129
920007	Ablator, HP 90°, 3mm	\$139
920023	2mm Ablator	\$159
920011	Ablator-S 90°, 3.5mm (suction)	\$159
920013	Ablator-S 60°, 3.5mm (suction)	\$159
920014	Ablator-S 2mm (suction)	\$159
920015	Ablator-S HP 90°, 3.5mm (suction)	\$159
Catalog #	Small Joint Probes with Integrated Cable	Price
920006	Micro Ablator	\$169
920016	Micro Ablator-S (suction)	\$169
920026	Micro Ablator-S High Profile (suction)	\$325
921002	Mini TAC	\$325
921004	Micro TAC-S	\$325
921009	Micro TAC-S Angled	\$140
923005	Micro Ligament Chisel - Angled	\$140
923006	Micro Ligament Chisel - Curved	\$140
923008	Micro Ligament Chisel - Hook	\$140
Catalog #	Hip Arthroscopy Probes, requires 8-pin Extension Cable	Price
910014	Ellex™ Ablator	\$499
911007	Ellex TAC-S	\$450
913007	Ellex Ligament Chisel	\$450
Catalog #	Generator	Price
815000	Vulcan® Generator Includes: footswitch and power cord	\$13,495
Catalog #	Accessories	Price
815001	Extension Cable* - 8 pin, autoclave, packaged ..	\$295
815002	Footswitch	\$495
805004	Probe Tip Bender*	\$85
815019	Split Electrode Pad	\$6

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INFORMATION

* Please refer to Sterilization Instructions on last page. Prices Subject to change without notice.
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770103 Rev. 07

ORA 0052434

U.S. Hospital Price List
Smith & Nephew ElectroThermal® Arthroscopy System® (EAS®)
Effective 04/24/2002

Catalog #	Saphyre Bipolar Ablation Probes	
925001	Saphyre™ 90°, 3mm	\$151
925003	Saphyre 60°, 3mm	\$151
925007	Saphyre 90°, 3mm High Profile	\$151
925011	Saphyre 90°, 3mm with Suction	\$172
925013	Saphyre 60°, 3mm with Suction	\$172
925015	Saphyre 90°, 3mm High Profile with Suction	\$172

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770103 Rev. 07

ORA 0052435

A 23207

U.S. Hospital Price List
Smith & Nephew ElectroThermal® Arthroscopy System® (EAS®)
Effective 04/24/2002

Ordering Information

Orders may be placed with our Customer Service Department:

Smith & Nephew	Toll Free: (888) 996-1996
3700 Haven Court	Telephone: (650) 369-9904
Menlo Park, CA 94025	Fax: (650) 369-9913

Terms

Shipments are F.O.B. Menlo Park, CA. Terms are net 30 days. All purchase orders are subject to acceptance by Smith & Nephew. In the event of conflicting terms, our terms will prevail. Prices are subject to change without notice. All applicable taxes will be added to the invoice. A finance charge may be assessed on all unpaid balances over 30 days at 18% per annum - 1 1/4 % per month.

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- Special order products.
- Merchandise held past 30 days from invoice date.
- Products not used before the expiration date or the "Use Before Date."
- Discontinued products.

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 - a. misuse, mishandling, and/or improper operation,
 - b. repairs or modification performed other than by Smith & Nephew or an Smith & Nephew authorized repair facility,
 - c. use in any manner or medical procedure, other than for which it is designed; and
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*** Sterilization Instructions**

For Extension cable - after proper cleaning.

Pre-vac: Wrapped four (4) minutes pre-vacuum steam exposure at 270-275° F (132-135°C)

Flash Gravity: Unwrapped ten (10) minutes at 132°C (acceptable range 131.5-133.5°C)

For Probe Benders - after proper cleaning.

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ORA 0052436

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770103 Rev. 07

A 23208

U.S. Hospital Price List
Smith & Nephew ElectroThermal® Arthroscopy System® (EAS®)
Effective 04/24/2002

Pre-vac: four (4) minutes pre-vacuum steam exposure at 270-275°F (132-135°C)

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INFORMATION**

ORA 0052437

Prices Subject to change without notice.

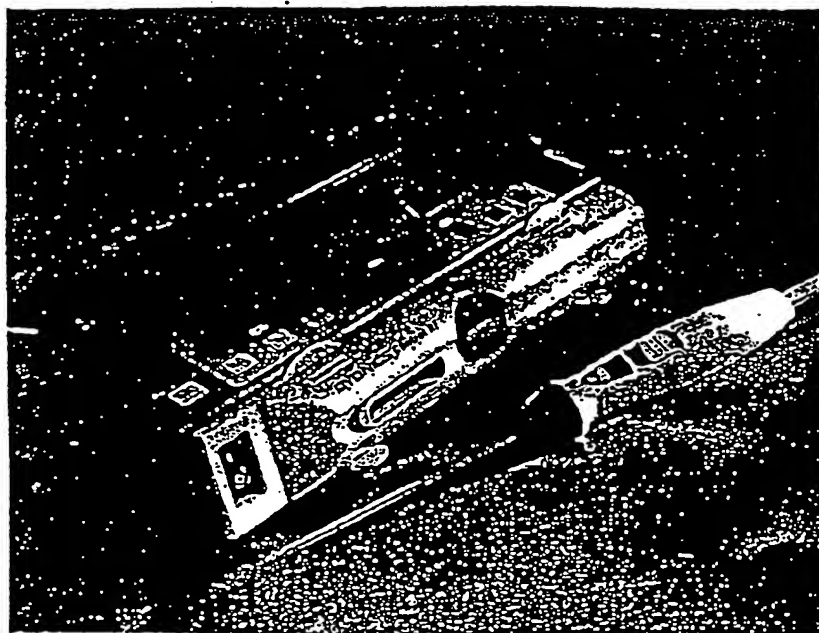
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770103 Rev. 07

A 23209

Dyonics® Control RF System

Arthroscopic Radiofrequency System



Sales Guide

Prepared by the
Marketing & Sales Training
Departments

ARTC 05530

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1

Plaintiff's
Trial Exhibit
PX 593
C.A.P. 0-00000

A 23586

Chapter 3: Recognizing Potential Customer Problems and Objectives

Categories of Potential Customer Objectives

Technical Objectives

- Easy to set-up for the OR staff
- Simple to use for both the OR staff and surgeon
- Reliable operation
- Minimal impact on current standard of care

Economic/Business/Organization Objectives

- Reduce OR downtime/increase OR turnover
- Simplify training requirements
- Enhance OR efficiency
- Reduce inventory levels

Medical Objectives

- Enhance patient outcomes by:
- Reducing the amount of bleeding
- Improving visualization during the procedures
- Increasing procedural speed to reduce anesthesia time

Customer Service Objectives

- Reliable operation, minimal need for follow-up service calls
- Prompt, knowledgeable service and support

Professional/Personal Objectives

- Cutting edge professional recognition
- Satisfied patients producing subsequent referrals

ARTC 05555

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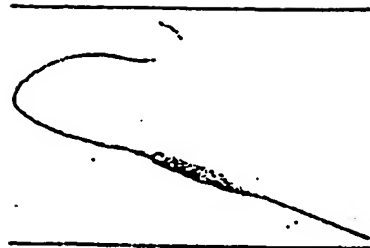
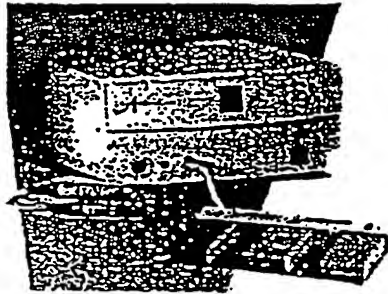
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A 23611

Competitive Review – ArthroCare

ArthroCare® System 2000

Product Definition



System 2000 Controller

- Single display for ablate and coag
- Non-adjustable 20W coag setting
- Ablate settings from 1 - 9

1 = 40W

2 = 50W

3 = 80W

4 = 100W

5 = 125W

6 = 160W

7 = 200W

8 = 240W

9 = 280W

- Bipolar operation

ArthroWand Probe

- Over 25 probe tip styles
- Right angles exceed 85% of sales
- 5 tip styles include suction
- 12.7 cm shaft length
- .0095" Turbovac electrode surface area
- Suction controlled with pinch clamp on tubing
- Reusable handpiece
- 3 pedal footswitch
- Ablate, coag and ablate adjuster

ArthroCare Strengths, Weaknesses and Competitive Strategy

Strengths

- First to market with bipolar ablation
- Broad product line
- Strong patent position

ARTC 05570

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41

A 23626

United States Patent (19)

Roos

(11) Patent Number: 4,706,667

(45) Date of Patent: Nov. 17, 1987

[54] ELECTRO SURGICAL HIGH FREQUENCY CUTTING INSTRUMENT

[75] Inventor: Eberhard Roos, Tuttingen, Fed. Rep. of Germany

[73] Assignee: Berchold Medizin-Elektronik GmbH & Co., Tuttingen, Fed. Rep. of Germany

[21] Appl. No.: 892,883

[22] Filed: Jul. 28, 1986

Related U.S. Application Data

[62] Division of Ser. No. 747,084, Jan. 20, 1985.

[30] Foreign Application Priority Data

Jan. 25, 1984 [DE] Fed. Rep. of Germany — 3423356

[51] Int. Cl. A61B 17/34

[52] U.S. Cl. 128/303.14; 128/303.17

[58] Field of Search 128/303.1, 303.13-303.17

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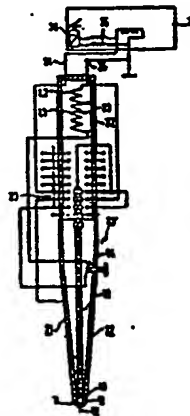
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Primary Examiner—William E. Kamm
Assistant Examiner—Max F. Hindenburg
Attorney, Agent, or Firm—Townsend and Townsend

ABSTRACT

[57] In an electro-surgical r.f. cutting instrument in which the neutral electrode (11) is arranged on both sides of the cutting electrode (12) but is however set back relative to the cutting electrode (12) on the instrument body (13). The ratio of the sizes of the contact areas (14, 15) of the neutral electrode (11) and of the cutting electrode (12) is greater than 7:1 and smaller than 20:1.

3 Claims, 4 Drawing Figures



Plaintiff's
Trial Exhibit
PX 605
C.A.M. 11-20-87

A 23658

FIG. 2

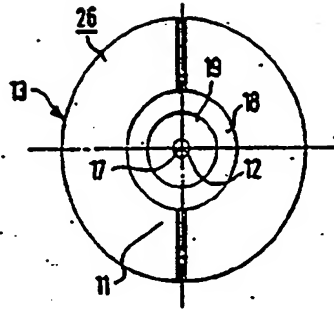
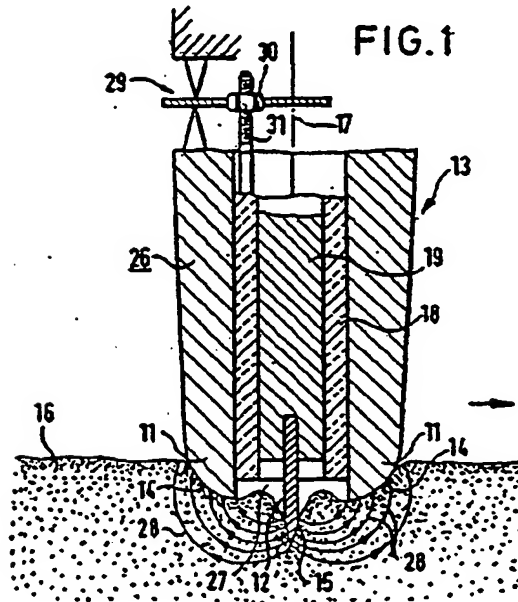


FIG. 1





ELECTRO SURGICAL HIGH FREQUENCY CUTTING INSTRUMENT

This is a division of application Ser. No. 747,086, filed June 20, 1983.

The invention relates to an electro-surgical high frequency cutting instrument comprising a preferably elongate instrument body from which, in the operative state, a small area cutting electrode projects forwardly, and a large area neutral electrode which can be brought into contact with the patient near to the cutting electrode.

In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for troublefree cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes.

The principal object of the invention is to provide an electro-surgical high frequency cutting instrument of the initially named kind in which current conditions which are largely precisely defined are present at the cutting electrode during the making of a cut substantially perpendicular to the longitudinal axis of the body of the instrument, with the current conditions ensuring a troublefree clean cut of the tissue without overheating of the tissue and without the tissue and the instrument sticking together.

In order to satisfy this object the invention provides that the neutral electrode is arranged on the instrument body on both sides of the cutting electrode, but set back relative to the cutting electrode, in such a way that it is supported on the tissue on both sides of the cutting electrode while the axially projecting cutting electrode penetrates into the tissue; and that the ratio of the sizes of the contact surfaces between the neutral electrode and the tissue on the one hand and between the cutting electrode and the tissue on the other hand, is greater than 7:1.

If, in a cutting instrument of this kind, a power of for example 5 to 10 Watts per mm² is applied to the cutting electrode then a power density occurs at the cutting electrode, which is preferably formed as a point, which is such that the heat necessary for tissue separation is generated in the tissue and in the tissue cells. The fact that the neutral electrode itself is likewise in current conducting contact with the tissue ensures a problem-free flow of current between the cutting electrode and the neutral electrode. In other words the transition resistance between the two electrodes is substantially constant. As a result of the larger area of the neutral electrode which is in contact with the tissue the power density at the neutral electrode is reduced so far that with normal cutting speeds of the order of several cm per sec. not even tissue heating, which could lead to coagulation, occurs. The neutral electrode thus slides smoothly over the tissue during cutting while the cut-

ting electrode, which is arranged directly alongside or between it, causes the required strong heating at the desired location of the cut that is necessary to execute a smooth cut. As the resistance between the cutting electrode and neutral electrode is largely constant the high frequency power of the generator can be regulated to a value at which overheating of the tissue is also effectively avoided in the area of the cutting electrode, but such that a clean cut is nevertheless obtained.

The radiofrequency cutting instrument of the invention is uncritical in its operation by the surgeon because a problem-free electric cut is effected through the cutting electrode even with irregular cutting speed, without tissue damage or adhesion occurring in the region of the neutral electrode.

In order to prevent the cutting instrument of the invention from becoming awkward to handle provision should further be made that the ratio of the sizes of the contact areas of the neutral electrode and of the cutting electrode is smaller than 20:1 and preferably smaller than 15:1.

One obtains particularly good electro-surgical cutting characteristics combined with a compact and slim construction of the instrument body if the ratio of the sizes of the contact surfaces of the neutral electrode and of the cutting electrode is approximately 10:1.

Although the cutting electrode could also have the form of a narrow blade, it is preferred for the cutting electrode to project substantially axially and preferably also in a straight line from the tip of the instrument body. If the cutting electrode is in addition formed with a sharp tip then the power density in the tip region is particularly large which is important for a smooth cut free of injury.

The depth of cut preferably amounts to 0.5 to 3 mm. The extent of the neutral electrode which surrounds the cutting electrode in the direction perpendicular to the axis of the instrument body preferably amounts from 2 to 6, in particular from 3 to 5 and most particularly to approximately 4 mm.

The cutting speed conveniently amounts to from 1 to 5, in particular from 2 to 4 and preferably to approximately 3 cm/sec.

The distance of the cutting electrode from the neutral electrode in the direction perpendicular to the axis of the instrument body usefully amounts to from 5 to 15 and in particular to approximately 10 mm.

When the cutting electrode has a needle-like tip this tip preferably has a diameter from 0.1 to 0.5, in particular of from 0.2 to 0.4 and particularly of approximately 0.3 mm. The cutting electrode preferably projects axially beyond the neutral electrode by from 1 to 5 mm.

The tip of the cutting electrode can usefully have a length from 2 to 5 mm and preferably of approximately 3 mm.

As electrical insulation is necessary between the two electrodes a preferred practical embodiment is usefully arranged in such a way that the cutting electrode projects axially from an insulating body arranged inside the neutral electrode.

In order to increase the path for leakage currents between the two electrodes an advantageous further embodiment of the invention is characterised in that the insulating body is set back axially relative to the contact surface of the neutral electrode.

Furthermore, a practical realization of the invention provides that the insulating body is formed as an insulating sleeve in which a metal rod is located which is

connected to the generator and which carries the cutting electrode.

With this arrangement it is also expedient if the metal rod is set back axially relative to the neutral electrode, and preferably also relative to the insulating sleeve, in order to further reduce losses by leakage currents directly between the two electrodes.

It is of particular advantage if the cutting electrode is axially displaceably arranged on the instrument body. In this way the depth of cut can be preselected by the operator before performing an electric cut, with the range of adjustment being advantageously selectable between 0.5 and 5 mm.

In one realization of the invention the neutral electrode can be circular cross-section and can concentrically surround the cutting electrode. In this case the instrument thus has approximately the shape of a pencil or stylus which can also be correspondingly held and guided by the operator. The metal tip which forms the cutting electrode projects from the bottom of the stylus at the center.

A further embodiment is constructed so that the neutral electrode is realized by the tips of the two limbs of a pincette or pair of tweezers which forms the insulating body. With this arrangement it is particularly expedient if the insulating sleeve with the cutting electrode can be retracted relative to the limbs of the pincette. In this manner the pincette can also be used without the cutting electrode of the invention.

Finally, this embodiment can be so further developed that the two branches of the pincette are insulated from one another, with a switch being provided which, when the cutting electrode and the insulating sleeve are retracted, connects the limbs to the two voltage bearing terminals of the r.f. generator.

As a result of this construction the cutting instrument can also be used for coagulation, it being necessary to take appropriate electrical matching measures at the r.f. generator.

In order to ensure injury-free sliding of the neutral electrode on the tissue surface during the cut the contact surface of the neutral electrode should be of appropriate smooth and rounded shape. In particular, the neutral electrode is made of substantially hemispherical rounded shape at its end which enters into contact with the tissue.

The invention will now be described in the following by way of example only and with reference to the drawing which shows:

FIG. 1 a partially sectioned sideview of an electrosurgical radio frequency cutting instrument in accordance with the invention in the tip region which contacts the tissue 16 of a patient.

FIG. 2 a view of the r.f. cutting instrument of FIG. 1 from below.

FIG. 3 a schematic, partially sectioned sideview of a further embodiment of and r.f. cutting instrument in accordance with the invention and shaped like a pincette, and

FIG. 4 a view similar to FIG. 3 of the same cutting instrument after switching over into the position provided for effecting coagulation.

As seen in FIGS. 1 and 2 a thin metal tip is used at the bottom of a cylindrical metal rod 19 as the cutting electrode 12. The cutting electrode 12 projects downwardly significantly beyond the metal rod 19. The metal rod 19 is concentrically sleeved by an insulating sleeve 18 which consists of a highly heat-resistant refractory

ceramic or teflon material. A thick-walled metal tube 26 is arranged in narrow contact around the insulating sleeve 18 and can be put together of two half shells as shown in FIG. 2. The metal tube is formed at the lower or front end of the instrument body 13 formed in this way as a semi-spherical head which forms the neutral electrode 11. The design of the neutral electrode 11 with a semi-spherical head has the purpose of ensuring better sliding on the tissue 16 during cutting in the direction of the arrow f in FIG. 1.

The metal rod 19, the insulating sleeve 18 and the neutral electrode 11 are axially displaced relative to one another in stepped manner in accordance with FIG. 1 in such a way that the path for leakage current between the metal rod 19 and the neutral electrode 11 is as long or large as possible. Moreover, a distinct intermediate space 27 should be formed between the tissue surface and the front end face of the metal rod 19 when placing the instrument body 13 onto the tissue 16 in accordance with FIG. 1, so that current largely flows starting from the tip of the cutting electrode 12 into the tissue 16.

The metal tube 26, the insulating sleeve 18 and the metal rod 19 with the cutting electrode 12 together form an arrangement concentric to the axis 17.

The metal rod 19 is connected to the one terminal of an r.f. generator (not shown) and the metal tube 26 to the other pole of the r.f. generator, which has a floating output not coupled to earth.

The manner of operation of the r.f. cutting instrument in accordance with the invention is as follows: The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small funnel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral electrode 11.

The dimensioning of the cutting electrode 12 and of the neutral electrode 11 is so selected that the contact areas 14, 15 have a ratio of approximately 10:1. If the instrument body 13 is now moved in the direction of the arrow f at a speed of approximately 3 cm/sec. over the tissue then a clean cut corresponding to the depth of penetration of the cutting electrode 12 will be formed in the tissue 16 without overheating or even adhesion occurring at the contact surface, because the current density close to the cutting electrode 12 is very high but rapidly reduces at a distance therefrom.

In order to adjust the depth of cut it is possible, in accordance with the invention, to axially displace either the metal rod 19 within the insulating sleeve 18 or, as assumed in FIG. 1, the insulating sleeve 18 within the metal tube 26, and to select a predetermined axial position relative to the metal tube 26 by an adjustment mechanism 29. The adjustment mechanism can for example consist of an adjustment nut 30 provided with a circular actuation disk which is arranged concentrically thereto, and of a threaded rod 31 which is connected with the insulating sleeve 18 for the transmission of axial forces. If the nut 30 is axially fixed to the metal tube 26, as indicated in FIG. 1, then really insulating sleeve 18 will be axially displaced relative to the metal tube 26 on rotation of the nut 30, which leads to a greater or lesser degree of projection of the cutting electrode 12 beyond the neutral electrode 11. The operator can thus prede-

terminate the cutting depth with which he wants to operate. This possibility of adjustment is particularly important because for certain electric operations the danger exists that on cutting too deeply into the tissue layers other organs will be unintentionally injured. By selecting particularly shallow depths of cut using the adjustment mechanism of the invention such injuries can be completely avoided without particular attention being required by the surgeon during electric cutting.

As seen in FIGS. 3 and 4 the neutral electrode 11 which surrounds the cutting electrode 12 on both sides is formed by the tip regions of the two limbs 21, 22 of a pincette 13', with the two limbs being mounted in the upper region on an insulating cap 32.

The insulating sleeve containing the metal rod 19 and the cutting electrode 12 is axially displaceably arranged within the insulating cap 32 in a manner not shown in such a way that it is either approximately flush with the neutral electrode 11 in the position of FIG. 3, with the cutting electrode 12 projecting axially forwardly in similar manner to that shown in FIG. 1, or lies clearly behind the ends of the limbs as shown in FIG. 4, so that the pincette 13' can also be used as a normal clamping instrument.

When the insulating sleeve 18 is advanced in accordance with FIG. 3 a r.f. cutting instrument in accordance with the invention is created in which the two limbs 21, 22 can be pressed from both sides against the insulating sleeve 18 by finger pressure.

A coil 33 with two windings L1 and L2 is built into the insulating cap 32. The one terminal of the winding L2 is connected with the earthed terminal 25 of the r.f. generator 20. The other terminal of the winding L2, which simultaneously produces the connection to the winding L1 is connected, in accordance with FIG. 4, to one contact of a closing switch 2 which forms one element of a multiple switch 23 actuated by displacement of the insulating sleeve 18. The other terminal of the winding L1 is connected with the one contact of the first normally open switch 1 (FIG. 4) and with the one contact of a further switch 4 of the multiple switch 23.

It should be pointed out that, for the sake of clarity, only those line connections are shown in FIGS. 3 and 4 which are necessary for the operation of the relevant switch position. In actual fact the electrical line connections which can be seen by jointly viewing FIGS. 3 and 4 are present between the various components.

The multiple switch 23 has in total eight fixed contact pairs and five displacement contacts which are located between the contact pairs on the insulating sleeve 18, which form the individual switches 1 to 8.

The other (left hand) contact of the individual switch 1 is connected with the hot terminal 24 of the r.f. generator 20. The other contact of the switch 2 is electrically conductively connected with the other contact of the switch 5 and also with the limb 21. The switch 3 is connected on the one side with the earthed terminal 25 of the r.f. generator 20 and on the other side with the limb 22 of the pincette 13'. The contacts of the switch 4 are connected to the one contact of the switch 1 and to the one contact of the hand switch 34. The contacts of the switch 5 are connected to the other contact of the hand switch 34 and to the other contact of the switch 2 and to the limb 21 respectively. The contacts of the switch 6 are connected to the cutting electrode 12 and to the one contact of the switch 8 and to the hot terminal 24 of the r.f. generator 20 respectively. The contacts of the switch 7 are connected to the earthed terminal 25

of the r.f. generator 20 and to the limb 21 respectively. The contacts of the switch 8 are connected with the one contact of the switch 5 and with the mentioned second contact of the hand switch 34 respectively.

The hand switch 34 serves to switch on the r.f. generator 20.

In the cutting position of FIG. 3 the full high frequency voltage is applied between the cutting electrode 12 and the neutral electrode 11 formed by the tip regions of the limbs 21, 22. The current flow from the r.f. generator 20 takes place via the poles 24, 25 in the manner shown in FIG. 3.

In accordance with the invention a low frequency control current with a low voltage is superimposed on the r.f. current. If the hand switch 34 is closed then this low frequency control current flows via the windings of the coil 33 which acts as an r.f. filter and further r.f. coupling coils 35 to a schematically illustrated switching relay 36 in the r.f. generator 20 which switches on the r.f. generator 20 when it engages. Thus, the r.f. generator 20 can be set in operation by closing the hand switch 34.

While the sliding contacts on the insulating sleeve 18 only close the switches 6, 7 and 8 in the cutting position of FIG. 3 these three switches are open in the coagulating position of FIG. 4 and in their place the switches 1 to 5 are closed. The insulating sleeve 18 is retracted in this position sufficiently far that the cutting electrode 11, which is here shaped like a needle, cannot come into contact with the tissue.

In the switch position of FIG. 4 the full r.f. voltage of the r.f. generator 20 is applied to the windings of the coil 33. The two limbs 21, 22 of the pincette are fully electrically insulated from one another in this position and receive a reduced r.f. voltage from the winding L2 of the coil 33. The voltage is thus stepped down (transformed).

If tissue is now clamped between the tip regions of the limbs 21, 22 and the r.f. generator 20 is again connected by closing the hand switch 34 then a r.f. current flows through the branches 21, 22 into the tissue and there generates the electrical heat losses necessary for coagulation.

In the switch position of FIG. 4 a low frequency control current for the switch-in relay 36 which is superimposed on the r.f. current also flows via the winding L1 of the coil 33 with L1 forming an element of a resonant circuit.

The load impedance for the cutting of FIG. 3 and for the coagulation of FIG. 4 is different. Whereas one can reckon with a load impedance of ca. 1000 Ohms during cutting the load impedance during coagulation amounts to approximately 50 to 100 Ohms. In order to obtain troublefree functioning in the various switch positions the output oscillating circuit of the r.f. generator 20 must be matched to these conditions respectively.

A particular advantage of the embodiment of FIGS. 3 and 4 lies in the fact that in the position of use for the cutting process the characteristic of the r.f. generator required for this application can be brought into effect, namely that the power increases with increasing resistance. In the position of use for coagulation in accordance with FIG. 4 a power characteristic results, brought about by the winding L2 of the coil 33, such that the power drops off with increasing resistance.

The r.f. generator 20 can also have an output decoupled from earth (floating output) with terminal 25 then no longer being connected to earth as shown in FIG. 3.

One of the essential advantages of the bipolar application technique of the invention is the reduced flow of leakage currents to earthed parts of the operating table which has been reduced to a non-dangerous minimum by the freedom of the patient current circuit from earthing and ground leaks.

I claim:

1. An electro-surgical apparatus for connecting to first and second outputs of an electrical generator comprising:

a first electrode comprising first and second generally elongate members, the members being spaced apart at one end and being displaceable relative to each other at the other end;

a second electrode disposed between the first and second members of the first electrode and being generally parallel thereto;

means for displacing the second electrode relative to the first electrode;

means for connecting the first output of the electrical generator to the first and second members of the first electrode and for connecting the second output of the electrical generator to the second electrode when the second electrode is displaced to a first position relative to the first electrode; and

means for alternately connecting the first output of the electrical generator to the first member of the first electrode and for connecting the second output of the electrical generator to the second member of the first electrode when the second electrode is displaced to a second position relative to the first electrode.

2. The apparatus according to claim 1 further comprising:

means for electrically insulating the members of the first electrode from each other; and

means for connecting the first output of the electrical generator to the first member of the first electrode and for connecting the second output of the electrical generator to the second member of the first electrode.

3. The apparatus according to claim 1 further comprising:

means for applying a first voltage to the first and second electrodes when the second electrode is displaced to the first position relative to the first electrode; and

means for applying a second voltage to the first and second members of the first electrode when the second electrode is displaced to the second position relative to the first electrode.

A 23665

United States Patent [19]

Roos

[11] Patent Number: 4,706,667

[45] Date of Patent: Nov. 17, 1987

[54] ELECTRO SURGICAL HIGH FREQUENCY CUTTING INSTRUMENT

[75] Inventor: Eberhard Roos, Tuttlingen, Fed. Rep. of Germany

[73] Assignee: Berchtold Medizin-Elektronik GmbH & Co., Tuttlingen, Fed. Rep. of Germany

[21] Appl. No.: 892,883

[22] Filed: Jul. 28, 1986

Related U.S. Application Data

[62] Division of Ser. No. 747,086, Jun. 20, 1985.

[30] Foreign Application Priority Data

Jun. 25, 1984 [DE] Fed. Rep. of Germany 3423356

[51] Int. Cl.⁴ A61B 17/36

[52] U.S. Cl. 128/303.14; 128/303.17

[58] Field of Search 128/303.1, 303.13-303.17

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Attorney, Agent, or Firm—Townsend and Townsend

[57] ABSTRACT

In an electro-surgical r.f. cutting instrument in which the neutral electrode (11) is arranged on both sides of the cutting electrode (12) but is however set back relative to the cutting electrode (12) on the instrument body (13). The ratio of the sizes of the contact areas (14, 15) of the neutral electrode (11) and of the cutting electrode (12) is greater than 7:1 and smaller than 20:1.

3 Claims, 4 Drawing Figures

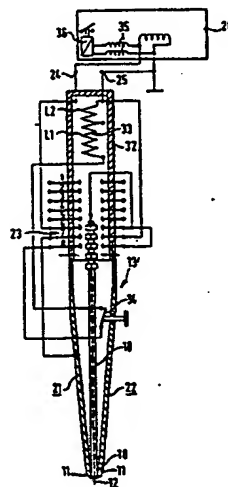


FIG. 2

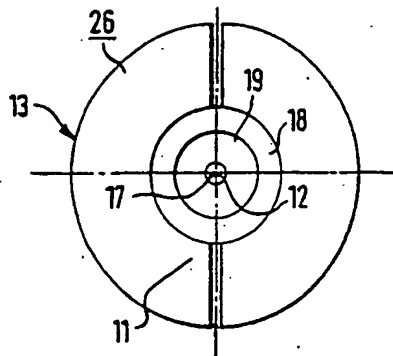
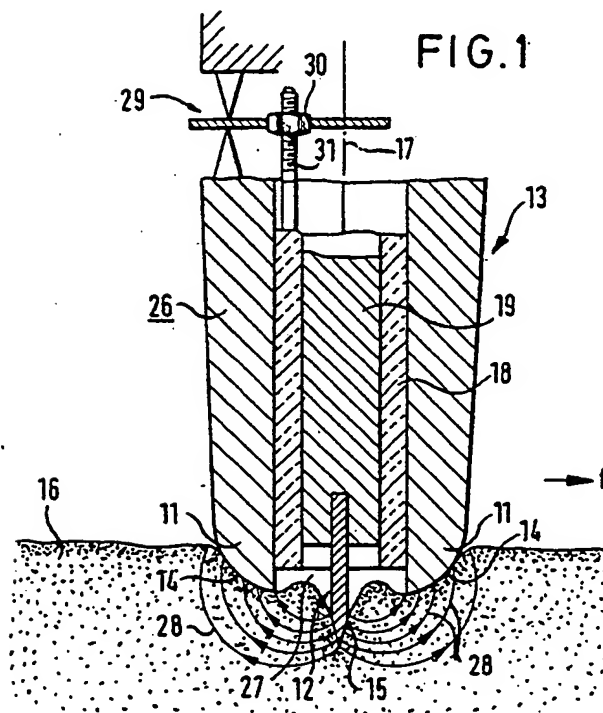
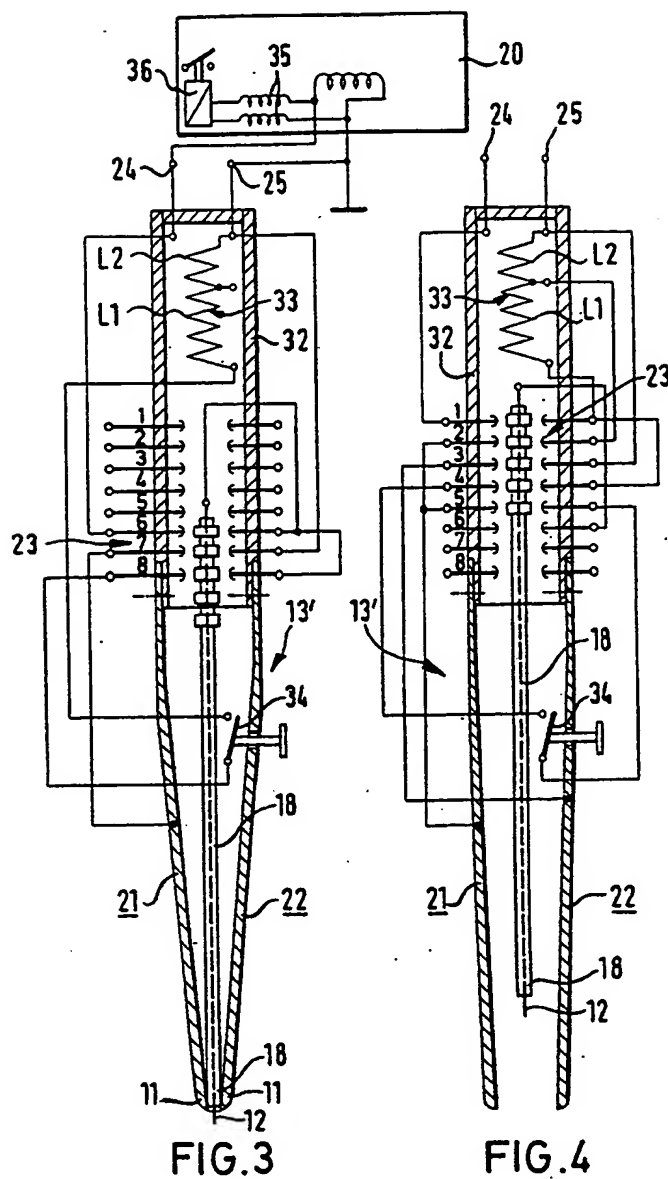


FIG. 1





ELECTRO SURGICAL HIGH FREQUENCY CUTTING INSTRUMENT

This is a division of application Ser. No. 747,086, filed June 20, 1985.

The invention relates to an electro-surgical high frequency cutting instrument comprising a preferably elongate instrument body from which, in the operative state, a small area cutting electrode projects forwardly, and a large area neutral electrode which can be brought into contact with the patient near to the cutting electrode.

In a known electro-surgical high frequency cutting instrument of this kind (DE-OS No. 25 21 719) the neutral electrode is admittedly arranged in the immediate vicinity of the cutting electrode, it is however so separated from the tissue by a plastic cover, or by its arrangement in an endoscope, that it can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process. As a result, it is difficult to maintain the current intensity required for troublefree cutting in a required precisely defined manner at the cutting electrode. Thus, if the power setting at the r.f. generator is too high, burns can result or, if the power setting is too low, then a poor cut or indeed injury occurs because the tissue to be cut sticks to the cutting electrode as a result of coagulation processes.

The principal object of the invention is to provide an electro-surgical high frequency cutting instrument of the initially named kind in which current conditions which are largely precisely defined are present at the cutting electrode during the making of a cut substantially perpendicular to the longitudinal axis of the body of the instrument, with the current conditions ensuring a troublefree clean cut of the tissue without overheating of the tissue and without the tissue and the instrument sticking together.

In order to satisfy this object the invention provides that the neutral electrode is arranged on the instrument body on both sides of the cutting electrode, but set back relative to the cutting electrode, in such a way that it is supported on the tissue on both sides of the cutting electrode while the axially projecting cutting electrode penetrates into the tissue; and that the ratio of the sizes of the contact surfaces between the neutral electrode and the tissue on the one hand and between the cutting electrode and the tissue on the other hand, is greater than 7:1.

If, in a cutting instrument of this kind, a power of for example 5 to 10 Watts per mm² is applied to the cutting electrode then a power density occurs at the cutting electrode, which is preferably formed as a point, which is such that the heat necessary for tissue separation is generated in the tissue and in the tissue cells. The fact that the neutral electrode itself is likewise in current conducting contact with the tissue ensures a problem-free flow of current between the cutting electrode and the neutral electrode. In other words the transition resistance between the two electrodes is substantially constant. As a result of the larger area of the neutral electrode which is in contact with the tissue the power density at the neutral electrode is reduced so far that with normal cutting speeds of the order of several cm per sec. not even tissue heating, which could lead to coagulation, occurs. The neutral electrode thus slides smoothly over the tissue during cutting while the cut-

ting electrode, which is arranged directly alongside or between it, causes the required strong heating at the desired location of the cut that is necessary to execute a smooth cut. As the resistance between the cutting electrode and neutral electrode is largely constant the high frequency power of the generator can be regulated to a value at which overheating of the tissue is also effectively avoided in the area of the cutting electrode, but such that a clean cut is nevertheless obtained.

The radiofrequency cutting instrument of the invention is uncritical in its operation by the surgeon because a problem-free electric cut is effected through the cutting electrode even with irregular cutting speed, without tissue damage or adhesion occurring in the region of the neutral electrode.

In order to prevent the cutting instrument of the invention from becoming awkward to handle provision should further be made that the ratio of the sizes of the contact areas of the neutral electrode and of the cutting electrode is smaller than 20:1 and preferably smaller than 15:1.

One obtains particularly good electro-surgical cutting characteristics combined with a compact and slim construction of the instrument body if the ratio of the sizes of the contact surfaces of the neutral electrode and of the cutting electrode is approximately 10:1.

Although the cutting electrode could also have the form of a narrow blade, it is preferred for the cutting electrode to project substantially axially and preferably also in a straight line from the tip of the instrument body. If the cutting electrode is in addition formed with a sharp tip then the power density in the tip region is particularly large which is important for a smooth cut free of injury.

The depth of cut preferably amounts to 0.5 to 5 mm. The extent of the neutral electrode which surrounds the cutting electrode in the direction perpendicular to the axis of the instrument body preferably amounts from 2 to 6, in particular from 3 to 5 and most particularly to approximately 4 mm.

The cutting speed conveniently amounts to from 1 to 5, in particular from 2 to 4 and preferably to approximately 3 cm/sec.

The distance of the cutting electrode from the neutral electrode in the direction perpendicular to the axis of the instrument body usefully amounts to from 5 to 15 and in particular to approximately 10 mm.

When the cutting electrode has a needle-like tip this tip preferably has a diameter from 0.1 to 0.5, in particular of from 0.2 to 0.4 and particularly of approximately 0.3 mm. The cutting electrode preferably projects axially beyond the neutral electrode by from 1 to 5 mm.

The tip of the cutting electrode can usefully have a length from 2 to 5 mm and preferably of approximately 3 mm.

As electrical insulation is necessary between the two electrodes a preferred practical embodiment is usefully arranged in such a way that the cutting electrode projects axially from an insulating body arranged inside the neutral electrode.

In order to increase the path for leakage currents between the two electrodes an advantageous further embodiment of the invention is characterised in that the insulating body is set back axially relative to the contact surface of the neutral electrode.

Furthermore, a practical realisation of the invention provides that the insulating body is formed as an insulating sleeve in which a metal rod is located which is

connected to the generator and which carries the cutting electrode.

With this arrangement it is also expedient if the metal rod is set back axially relative to the neutral electrode, and preferably also relative to the insulating sleeve, in order to further reduce losses by leakage currents directly between the two electrodes.

It is of particular advantage if the cutting electrode is axially displaceably arranged on the instrument body. In this way the depth of cut can be preselected by the operator before performing an electric cut, with the range of adjustment being advantageously selectable between 0.5 and 5 mm.

In one realization of the invention the neutral electrode can be circular cross-section and can concentrically surround the cutting electrode. In this case the instrument thus has approximately the shape of a pencil or stylus which can also be correspondingly held and guided by the operator. The metal tip which forms the cutting electrode projects from the bottom of the stylus at the center.

A further embodiment is constructed so that the neutral electrode is realised by the tips of the two limbs of a pincette or pair of tweezers which forms the insulating body. With this arrangement it is particularly expedient if the insulating sleeve with the cutting electrode can be retracted relative to the limbs of the pincette. In this manner the pincette can also be used without the cutting electrode of the invention.

Finally, this embodiment can be so further developed that the two branches of the pincette are insulated from one another, with a switch being provided which, when the cutting electrode and the insulating sleeve are retracted connects the limbs to the two voltage bearing terminals of the r.f. generator.

As a result of this construction the cutting instrument can also be used for coagulation, it being necessary to take appropriate electrical matching measures at the r.f. generator.

In order to ensure injury-free sliding of the neutral electrode on the tissue surface during the cut the contact surface of the neutral electrode should be of appropriate smooth and rounded shape. In particular, the neutral electrode is made of substantially hemispherical rounded shape at its end which enters into contact with the tissue.

The invention will now be described in the following by way of example only and with reference to the drawing which shows:

FIG. 1 a partially sectioned sideview of an electrosurgical radio frequency cutting instrument in accordance with the invention in the tip region which contacts the tissue 16 of a patient,

FIG. 2 a view of the r.f. cutting instrument of FIG. 1 from below,

FIG. 3 a schematic, partially sectioned sideview of a further embodiment of an r.f. cutting instrument in accordance with the invention and shaped like a pincette, and

FIG. 4 a view similar to FIG. 3 of the same cutting instrument after switching over into the position provided for effecting coagulation.

As seen in FIGS. 1 and 2 a thin metal tip is used at the bottom of a cylindrical metal rod 19 as the cutting electrode 12. The cutting electrode 12 projects downwardly significantly beyond the metal rod 19. The metal rod 19 is concentrically sleeved by an insulating sleeve 18 which consists of a highly heat-resistant refractory

ceramic or teflon material. A thick-walled metal tube 26 is arranged in narrow contact around the insulating sleeve 18 and can be put together of two half shells as shown in FIG. 2. The metal tube is formed at the lower or front end of the instrument body 13 formed in this way as a semi-spherical head which forms the neutral electrode 11. The design of the neutral electrode 11 with a semi-spherical head has the purpose of ensuring better sliding on the tissue 16 during cutting in the direction of the arrow f in FIG. 1.

The metal rod 19, the insulating sleeve 18 and the neutral electrode 11 are axially displaced relative to one another in stepped manner in accordance with FIG. 1 in such a way that the path for leakage current between the metal rod 19 and the neutral electrode 11 is as long or large as possible. Moreover, a distinct intermediate space 27 should be formed between the tissue surface and the front end face of the metal rod 19 when placing the instrument body 13 onto the tissue 16 in accordance with FIG. 1, so that current largely flows starting from the tip of the cutting electrode 12 into the tissue 16.

The metal tube 26, the insulating sleeve 18 and the metal rod 19 with the cutting electrode 12 together form an arrangement concentric to the axis 17.

The metal rod 19 is connected to the one terminal of an r.f. generator (not shown) and the metal tube 26 to the other pole of the r.f. generator, which has a floating output not coupled to earth.

The manner of operation of the r.f. cutting instrument in accordance with the invention is as follows: The instrument is first of all placed in accordance with FIG. 1 onto the tissue 16 which is to be separated by means of a cut, with a concave ring-like contact surface 14 being formed between the tissue 16 and the neutral electrode 11 and with a very small funnel-like contact surface 15 being formed between the tip of the cutting electrode 12 and the tissue 16. If the r.f. generator is now switched on then an r.f. current indicated by the current lines 28 flows between the cutting electrode 12 and the neutral electrode 11.

The dimensioning of the cutting electrode 12 and of the neutral electrode 11 is so selected that the contact areas 14, 15 have a ratio of approximately 10:1. If the instrument body 13 is now moved in the direction of the arrow f at a speed of approximately 3 cm/sec. over the tissue then a clean cut corresponding to the depth of penetration of the cutting electrode 12 will be formed in the tissue 16 without overheating or even adhesion occurring at the contact surface, because the current density close to the cutting electrode 12 is very high but rapidly reduces at a distance therefrom.

In order to adjust the depth of cut it is possible, in accordance with the invention, to axially displace either the metal rod 19 within the insulating sleeve 18 or, as assumed in FIG. 1, the insulating sleeve 18 within the metal tube 26, and to select a predetermined axial position relative to the metal tube 26 by an adjustment mechanism 29. The adjustment mechanism can for example consist of an adjustment nut 30 provided with a circular actuation disk which is arranged concentrically thereto, and of a threaded rod 31 which is connected with the insulating sleeve 18 for the transmission of axial forces. If the nut 30 is axially fixed to the metal tube 26, as indicated in FIG. 1, then really insulating sleeve 18 will be axially displaced relative to the metal tube 26 on rotation of the nut 30, which leads to a greater or lesser degree of projection of the cutting electrode 12 beyond the neutral electrode 11. The operator can thus prede-

termine the cutting depth with which he wants to operate. This possibility of adjustment is particularly important because for certain electric operations the danger exists that on cutting too deeply into the tissue layers other organs will be unintentionally injured. By selecting particularly shallow depths of cut using the adjustment mechanism of the invention such injuries can be completely avoided without particular attention being required by the surgeon during electric cutting.

As seen in FIGS. 3 and 4 the neutral electrode 11 which surrounds the cutting electrode 12 on both sides is formed by the tip regions of the two limbs 21, 22 of a pincette 13', with the two limbs being mounted in the upper region on an insulating cap 32.

The insulating sleeve containing the metal rod 19 and the cutting electrode 12 is axially displaceably arranged within the insulating cap 32 in a manner not shown in such a way that it is either approximately flush with the neutral electrode 11 in the position of FIG. 3, with the cutting electrode 12 projecting axially forwardly in similar manner to that shown in FIG. 1, or lies clearly behind the ends of the limbs as shown in FIG. 4, so that the pincette 32 can also be used as a normal clamping instrument.

When the insulating sleeve 18 is advanced in accordance with FIG. 3 a r.f. cutting instrument in accordance with the invention is created in which the two limbs 21, 22 can be pressed from both sides against the insulating sleeve 18 by finger pressure.

A coil 33 with two windings L1 and L2 is built into the insulating cap 32. The one terminal of the winding L2 is connected with the earthed terminal 25 of the r.f. generator 20. The other terminal of the winding L2, which simultaneously produces the connection to the winding L1 is connected, in accordance with FIG. 4, to one contact of a closing switch 2 which forms one element of a multiple switch 23 actuated by displacement of the insulating sleeve 18. The other terminal of the winding L1 is connected with the one contact of the first normally open switch 1 (FIG. 4) and with the one contact of a further switch 4 of the multiple switch 23.

It should be pointed out that, for the sake of clarity, only those line connections are shown in FIGS. 3 and 4 which are necessary for the operation of the relevant switch position. In actual fact the electrical line connections which can be seen by jointly viewing FIGS. 3 and 4 are present between the various components.

The multiple switch 23 has in total eight fixed contact pairs and five displacement contacts which are located between the contact pairs on the insulating sleeve 18, which form the individual switches 1 to 8.

The other (left hand) contact of the individual switch 1 is connected with the hot terminal 24 of the r.f. generator 20. The other contact of the switch 2 is electrically conductively connected with the other contact of the switch 5 and also with the limb 21. The switch 3 is connected on the one side with the earthed terminal 25 of the r.f. generator 20 and on the other side with the limb 22 of the pincette 13'. The contacts of the switch 4 are connected to the one contact of the switch 1 and to the one contact of the hand switch 34. The contacts of the switch 5 are connected to the other contact of the hand switch 34 and to the other contact of the switch 2 and to the limb 21 respectively. The contacts of the switch 6 are connected to the cutting electrode 12 and to the one contact of the switch 8 and to the hot terminal 24 of the r.f. generator 20 respectively. The contacts of the switch 7 are connected to the earthed terminal 25

of the r.f. generator 20 and to the limb 21 respectively. The contacts of the switch 8 are connected with the one contact of the switch 5 and with the mentioned second contact of the hand switch 34 respectively.

The hand switch 34 serves to switch on the r.f. generator 20.

In the cutting position of FIG. 3 the full high frequency voltage is applied between the cutting electrode 12 and the neutral electrode 11 formed by the tip regions of the limbs 21, 22. The current flow from the r.f. generator 20 takes place via the poles 24, 25 in the manner shown in FIG. 3.

In accordance with the invention a low frequency control current with a low voltage is superimposed on the r.f. current. If the hand switch 34 is closed then this low frequency control current flows via the windings of the coil 33 which acts as an r.f. filter and further r.f. coupling coils 35 to a schematically illustrated switching relay 36 in the r.f. generator 20 which switches on the r.f. generator 20 when it engages. Thus, the r.f. generator 20 can be set in operation by closing the hand switch 34.

While the sliding contacts on the insulating sleeve 18 only close the switches 6, 7 and 8 in the cutting position of FIG. 3 these three switches are open in the coagulating position of FIG. 4 and in their place the switches 1 to 5 are closed. The insulating sleeve 18 is retracted in this position sufficiently far that the cutting electrode 11, which is here shaped like a needle, cannot come into contact with the tissue.

In the switch position of FIG. 4 the full r.f. voltage of the r.f. generator 20 is applied to the windings of the coil 33. The two limbs 21, 22 of the pincette are fully electrically insulated from one another in this position and receive a reduced r.f. voltage from the winding L2 of the coil 33. The voltage is thus stepped down (transformed).

If tissue is now clamped between the tip regions of the limbs 21, 22 and the r.f. generator 20 is again connected by closing the hand switch 34 then a r.f. current flows through the branches 21, 22 into the tissue and there generates the electrical heat losses necessary for coagulation.

In the switch position of FIG. 4 a low frequency control current for the switch-in relay 36 which is superimposed on the r.f. current also flows via the winding L1 of the coil 33 with L1 forming an element of a resonant circuit.

The load impedance for the cutting of FIG. 3 and for the coagulation of FIG. 4 is different. Whereas one can reckon with a load impedance of ca. 1000 Ohms during cutting the load impedance during coagulation amounts to approximately 50 to 100 Ohms. In order to obtain troublefree functioning in the various switch positions the output oscillating circuit of the r.f. generator 20 must be matched to these conditions respectively.

A particular advantage of the embodiment of FIGS. 3 and 4 lies in the fact that in the position of use for the cutting process the characteristic of the r.f. generator required for this application can be brought into effect, namely that the power increases with increasing resistance. In the position of use for coagulation in accordance with FIG. 4 a power characteristic results, brought about by the winding L2 of the coil 33, such that the power drops off with increasing resistance.

The r.f. generator 20 can also have an output decoupled from earth (floating output) with terminal 25 then no longer being connected to earth as shown in FIG. 3.

One of the essential advantages of the bipolar application technique of the invention is the reduced flow of leakage currents to earthed parts of the operating table which has been reduced to a non-dangerous minimum by the freedom of the patient current circuit from earthing and ground leaks.

I claim:

1. An electro-surgical apparatus for connecting to first and second outputs of an electrical generator comprising:

a first electrode comprising first and second generally elongate members, the members being spaced apart at one end and being displaceable relative to each other at the other end;

a second electrode disposed between the first and second members of the first electrode and being generally parallel thereto;

means for displacing the second electrode relative to the first electrode;

means for connecting the first output of the electrical generator to the first and second members of the first electrode and for connecting the second output of the electrical generator to the second electrode when the second electrode is displaced to a first position relative to the first electrode; and

means for alternately connecting the first output of the electrical generator to the first member of the first electrode and for connecting the second output of the electrical generator to the second member of the first electrode when the second electrode is displaced to a second position relative to the first electrode.

2. The apparatus according to claim 1 further comprising:

means for electrically insulating the members of the first electrode from each other; and

means for connecting the first output of the electrical generator to the first member of the first electrode and for connecting the second output of the electrical generator to the second member of the first electrode.

3. The apparatus according to claim 1 further comprising:

means for applying a first voltage to the first and second electrodes when the second electrode is displaced to the first position relative to the first electrode; and

means for applying a second voltage to the first and second members of the first electrode when the second electrode is displaced to the second position relative to the first electrode.

* * * * *

(525)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

2004 JUL -8 PM 3:44

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

SMITH & NEPHEW, INC.,

Counterclaim Plaintiff,

v.

ARTHROCARE CORPORATION, AND
ETHICON, INC.,

Counterclaim Defendants.

SMITH & NEPHEW'S SECOND NOTICE OF APPEAL

PLEASE TAKE NOTICE that Smith & Nephew, Inc. ("Smith & Nephew"), defendant and counterclaim-plaintiff in the above-captioned case, hereby appeals to the United States Court of Appeals for the Federal Circuit from:

(1) the Order, dated June 9, 2004, and the Amended Order, dated June 24, 2004, enjoining Smith & Nephew from infringing, contributing to the infringement of, and/or inducing the infringement of the patents-in-suit, and ordering Smith & Nephew to take certain actions (D.I. 522, 524);

(2) the Order and Memorandum Opinion, dated April 27, 2004, and the Revised Order, dated April 28, 2004, denying Smith & Nephew's motion for reconsideration of orders granting ArthroCare Corp.'s ("ArthroCare") motion for

permanent injunction and denying Smith & Nephew's motion to stay the injunction pending appeal (D.I. 507, 508, and 509);

(3) the Revised Order, dated April 27, 2004, dismissing Smith & Nephew's antitrust counterclaim and granting ArthroCare's motion to dismiss that counterclaim (D.I. 506);

(4) the Order, dated April 8, 2004, denying Smith & Nephew's unopposed motion to lift the stay to oppose ArthroCare's motion to dismiss the antitrust counterclaim (D.I. 499);

(5) the Orders and Memorandum Opinions, dated March 10, 2004, denying Smith & Nephew's motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b), denying Smith & Nephew's motion for a new trial, denying Smith & Nephew's cross motion to strike motion for entry of judgment of no inequitable conduct, granting ArthroCare's motion for entry of judgment of no inequitable conduct, granting ArthroCare's motion for permanent injunction, and granting ArthroCare's motion to dismiss Smith & Nephew's antitrust counterclaim (D.I. 481, 482, 483, 484);

(6) the Judgment for ArthroCare against Smith & Nephew, dated June 20, 2003 (D.I. 452);

(7) those portions of the Memorandum Order, dated April 9, 2003, construing the disputed claim language in U.S. Patents '536, '882 and '592 in a manner that differed from that proposed by Smith & Nephew (D.I. 353); and

(8) each and every order, opinion, ruling, finding and/or conclusion of the District Court which produced or is subsumed within those portions of such Judgment, Orders, Memorandum Opinions and/or Memorandum Order, and/or was adverse to Smith & Nephew.

Enclosed herewith is a \$250 docketing fee required by 28 U.S.C. § 1913 and the \$5 filing fee required by 28 U.S.C. §1917.

Dated: July 8, 2004

FISH & RICHARDSON P.C.

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A 26341

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of July, 2004, a true and correct copy of the foregoing SMITH & NEPHEW'S SECOND NOTICE OF APPEAL was caused to be served on the attorneys of record at the following addresses as indicated:

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A 26342

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June 8, 2004

BY HAND


The Honorable Sue L. Robinson
United States District Court
844 King Street
Wilmington, DE 19801

Re: ArthroCare v. Smith & Nephew
C.A. No. 01-504 (SLR)

Dear Chief Judge Robinson:

Enclosed is a copy of the June 3, 2004 Order of the Federal Circuit, denying Smith & Nephew's motion for a stay of the injunction pending appeal, which Ms. Margolis referred to during the telephone conference this morning.

Respectfully,


Jack B. Blumenfeld

JBB/bls

cc: Peter T. Dalleo, Clerk (By Hand)
William J. Marsden, Jr., Esquire (By Hand)
John G. Day, Esquire (By Hand)
Jared Bobrow, Esquire (By Fax)
Ruffin B. Cordell, Esquire (By Fax)
Vicki Margolis, Esquire (By Fax)

A 26642

NOTE: Pursuant to Fed. Cir. R. 47.6, this order
is not citable as precedent. It is a public order.

United States Court of Appeals for the Federal Circuit

04-1323

ARTHROCARE CORPORATION,

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

ON MOTION

Before NEWMAN, LOURIE, and CLEVINGER, Circuit Judges.

LOURIE, Circuit Judge.

ORDER

Smith & Nephew, Inc. moves for a stay, pending appeal, of the permanent injunction issued by the United States District Court for the District of Delaware. ArthroCare Corporation opposes. Smith & Nephew replies.

ArthroCare sued Smith & Nephew for infringement of three patents relating to electrosurgical devices and methods. The jury returned a verdict of infringement and

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rejected Smith & Nephew's assertions of invalidity. Subsequently, the district court granted ArthroCare's motion for entry of a permanent injunction. Smith & Nephew moves for a stay of the injunction, pending disposition of its appeal.

In deciding whether to grant a stay, pending appeal, this court "assesses the movant's chances of success on the merits and weighs the equities as they affect the parties and the public." E. I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 835 F.2d 277, 278 (Fed. Cir. 1987). See also Standard Havens Prods. v. Gencor Indus., 897 F.2d 511 (Fed. Cir. 1990). To prevail, a party moving for a stay, pending appeal, must establish a strong likelihood of success on the merits or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor. Hilton v. Braunskill, 481 U.S. 770, 778 (1987).

Smith & Nephew argues that it has established a strong likelihood of success on the merits or, at a minimum, demonstrated a substantial case on the merits on several grounds. For purposes of this motion, we discuss Smith & Nephew's first and primary argument. Smith & Nephew asserts that it was denied due process because the district court did not allow Smith & Nephew to file a response to ArthroCare's motion to dismiss Smith & Nephew's antitrust counterclaims before granting the motion. ArthroCare points out that Smith & Nephew had the opportunity to respond, and did, in the motion for reconsideration, and that the district court considered Smith & Nephew's arguments in that context and found them unavailing. Based on the papers submitted, Smith & Nephew has not met its burden of establishing a strong likelihood of success or a substantial question on that issue or the other issues raised. See Hilton, 481 U.S. at 778. Therefore a stay, pending appeal, is not warranted.

Accordingly,

IT IS ORDERED THAT:

The motion is denied.

FOR THE COURT

JUN - 3 2004

Date

Alan D. Lourie

Alan D. Lourie
Circuit Judge

cc: Ruffin B. Cordell, Esq.
Jared Bobrow, Esq.
George F. Pappas, Esq.

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THE FEDERAL CIRCUIT

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